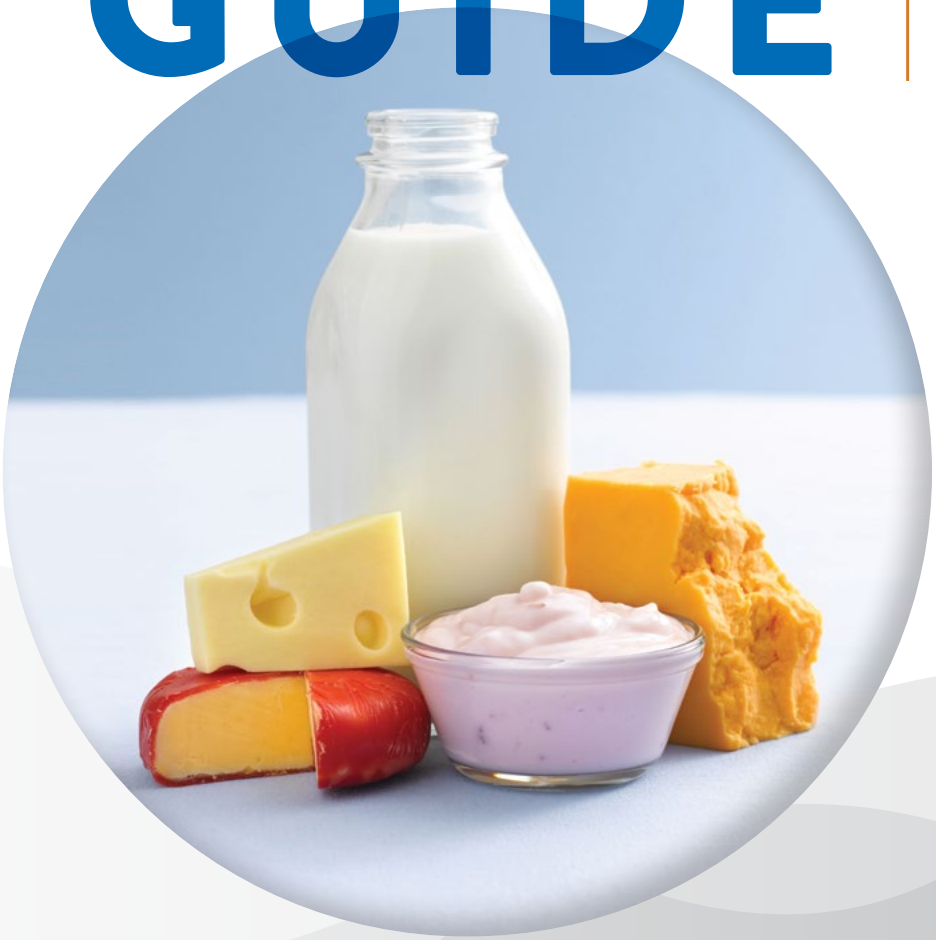
NATIONAL DAIRY COUNCIL® QUICK-REFERENCE GUIDE

Nutrition Claims For Dairy Products



NATIONAL DAIRY COUNCIL™

National Dairy Council® (NDC), the non-profit organization founded by dairy farmers and funded by the national dairy checkoff program, has been committed to research-based nutrition education and communications since its start in 1915. NDC is dedicated to bringing to life the dairy community's shared vision of a healthy, happy, sustainable world – with science as its foundation. NDC's staff of registered dietitians, communicators and scientists specialize in nutrition, product and environmental research, which anchors NDC's commitment to a prosperous future for people, communities and the planet. NDC educates about how nutrient-rich, responsibly produced dairy foods like milk, cheese, yogurt and dairy ingredients help nourish life. For more information, visit www.USDairy.com and follow NDC on Facebook and Twitter (@NtlDairyCouncil).

Revised by DMI Regulatory Affairs and Product Research Team

QUICK-REFERENCE GUIDE TO NUTRITION CLAIMS FOR DAIRY PRODUCTS

This Quick-Reference Guide made available by National Dairy Council provides a basic understanding of nutrition and health-related claims that represent potential opportunities for use with milk[1] and milk products.

Milk, cheese and yogurt combined provide

52% of calcium

51% of vitamin D

14% of potassium

17% of protein

and at least

25% of vitamin A, vitamin B12, and phosphorous to the the average American diet

The average consumption of milk, cheese and yogurt provide Americans 2 years and older 52% of their calcium, 51% of their vitamin D, 14% of their potassium, 17% of their protein and at least 25% of their vitamin A, vitamin B12 and phosphorus. The significant contribution of essential nutrients is provided at an average 220 calories, 15% of total fat, 26% of saturated fat, 11% of sodium and only 2% of added sugars per day.[2] Milk is a leading food source of nutrients of public health concern,[3] including calcium, vitamin D and potassium, and with the vast body of scientific evidence supporting the role of dairy foods in a healthy diet, there are many opportunities for claims.

When making claims on food labels or collateral materials, it is important to remember that compliance with regulatory requirements and industry standards set forth by the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC) and other governing agencies is critical. *This reference guide is not a comprehensive guide to all federal, state and city regulations and should not be considered as such.* More information on FDA regulations can be found in the Code of Federal Regulations, Title 21. All product-related claims must be substantiated and in compliance with regulations before being used in labeling or advertising. As regulations are subject to change over time, it is imperative that the most current regulations be consulted prior to making any claims. **NDC strongly encourages any company to obtain appropriate legal advice specific to its contemplated activities to ensure compliance with all applicable regulations prior to making any claims.**

The Federal Food, Drug and Cosmetic Act of 1938 (FFDCA) established the major elements of today's FDA food regulations. The premise of FFDCA was based on the concepts of adulteration (preventing harmful substances in food) and misbranding (preventing false or misleading statements on food labels). The FFDCA authorized the FDA to establish food standards of identity and introduce key enforcement tools (seizures, injunctions, criminal prosecutions) and interstate commerce (reflecting the national scope of food production and distribution). The Nutrition Labeling and Education Act (NLEA) of 1990 amended the FFDCA, affirming the FDA's authority to mandate nutrition labeling on most foods and clarifying the agency's role in regulating nutrient content claims and health claims on food labels. In 2016, the NLEA was amended to reflect the current understanding of nutrition science as well as the reality of how people eat and drink.

The 2016 amended NLEA required changes to the Nutrition Facts Label for packaged foods and beverages. These changes include a refreshed design and updated information to provide ease in making informed food choices that contribute to lifelong healthy eating habits. The key updated information includes some serving size changes to reflect the amount people typically eat and drink today (Reference Amount Customarily Consumed (RACC)), larger and bolder calorie information, removal of calories from fat, addition of added sugars in grams and as a percent Daily Value (%DV), updates to the list of nutrients that are required or permitted on the label (e.g., vitamin D and potassium are now required and vitamins A and C are no longer required) and change the footnote at the bottom of the label to better explain the meaning of %DV. In addition, many of the Daily Reference Values (DRV) and Recommended Daily Intakes (RDI), which are used to calculate %DV, changed to reflect updated recommendations for the nutrient needs for the U.S. population. Even though the amount of a specific nutrient (or nutrients) in a food or beverage did not change, the change in DV impacted the %DV the product provides and the nutrient content claims that could be made. This Quick-Reference Guide reflects the most updated food regulations as of November 2022.

1 Milk is defined by regulation, see 21 CFR § 131.110 (a).

2 National Dairy Council. NHANES 2014-2018. Data Source: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services. http://www.cdc.gov/nchs/nhanes.htm.

3 Keast DR et al. Nutrients 2013;5:283-301; O'Neil CE et al. Nutrients 2012;4:2097-2120.

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REGULATORY OVERSIGHT

Marketing messages and claims are regulated under Federal and state laws and subject to industry self-regulation. At the Federal level, the agencies with primary jurisdiction over marketing messages are the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC).

FDA's oversight covers food labels and labeling, including nutrition and health claims. The *label* is the printed material upon a food's immediate container and other printed material on any consumer product container or wrapper (e.g., an outer carton or a neck tag).[4] *Labeling* refers to materials accompanying the food (e.g. shelf tags and point-of-sale flyers) and through the Agencies' exercise of enforcement, can include company websites and social media platforms.[5] FDA and FTC share enforcement of the regulations as the claims appear on company websites and social media as well as television and radio advertising to more efficiently use their limited resources.

FDA's oversight of claims made on labels or in labeling is focused on (1) whether the claims are used in accordance with applicable regulations, and (2) whether the claims made for food products promote those products for use as a drug in disease treatment (*e.g.*, Juice for Fighting Colds & Flu). FDA provides guidance to assist in determining when a statement is a drug claim, that is, a claim to diagnose, cure, mitigate, treat or prevent disease or damage to the body.

The FTC focuses its oversight of product claims on whether claims are truthful and not misleading. FDA and FTC have both adopted the same "credible and reliable evidence" standard to ensure that the truthfulness of claims made is appropriately substantiated by scientific evidence. The FTC is responsible for protecting consumers from unfair or deceptive acts or practices and oversees food advertising, which includes materials available on the internet. FTC's oversight broadly covers advertising materials, promotional activities, marketing and sales practices in general, and includes traditional print, television, telephone and radio advertising as well as materials provided on the internet for the purposes of promoting the sale of a product. The FTC periodically joins with other law enforcement agencies to monitor the internet for potentially false or deceptive online advertising claims. When advertising materials do not comply with the law, enforcement actions may be taken.

Environmental marketing claims, which are overseen by the FTC, are applicable broadly across all types of communications including advertisements, labels, package inserts, promotional materials, symbols, emblems, logos, depictions, product brand names and marketing through traditional, electronic and other media such as the internet or email. FTC provides industry guidance, commonly known as the *Green Guides*.[6] The Green Guides were first issued in 1992 and were revised in 1996, 1998 and 2012. The most recent update of the Guides includes new guidance on markets' use of product certifications and seals of approval, claims about materials and energy sources that are renewable and carbon offset claims. Some environmental-related claims are also overseen by the United States Department of Agriculture (USDA), such as *organic* or the use of *free-range* or *natural* in labeling of meat, poultry and egg products.

The FTC evaluates "made in the USA" claims along with other country of origin claims as does the USDA and Customs and Border Protection (CBP).

Many states have enacted their own food and drug statutes that may govern marketing messages and claims. These statues often mirror Federal laws, so a violation of Federal law may often also be a violation of state law.

In addition to Federal and state laws, marketing messages and claims are subject to industry self-regulation through mechanisms such as the National Advertising Division (NAD) or the Children's Advertising Review Unit (CARU). A further check on marketing activities is the threat of complaints or lawsuits for false advertising brought by competitors.

4 21 U.S.C. 321(k); 21 CFR 1.3
5 21 U.S.C. 321(m)
6 16 CFR § 260

USEFUL RESOURCES

USDA Guidelines for AMS Oversight of Commodity Research and Promotion Programs
https://www.ams.usda.gov/sites/default/files/media/RPGUIDELINES092015.pdf

Code of Federal Regulations, Title 21, Food and Drugs
http://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

FDA Food Labeling Guide (As of October 2022) FDA has not updated this website to the 2016 regulations
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm

FDA Changes to the Nutrition Facts Label
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

FTC Resources
https://www.ftc.gov/tips-advice/business-center/advertising-and-marketing

FTC Enforcement Policy Statement on Food Advertising
https://www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising

FTC Policy Statement Regarding Advertising Substantiation
https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation

Guides for the Use of Environmental Marketing Claims ("Green Guides")
https://www.ftc.gov/policy/federal-register-notices/guides-use-environmental-marketing-claims-green-guides

SELECT DEFINITIONS FOR U.S. NUTRIENT GOALS

Daily Value (DV) / Percent Daily Value (%DV)

In order to limit consumer confusion, nutrition facts labels include a single nutrient heading, Daily Value (DV), to designate both the Daily Reference Values (DRV) and Reference Daily Intake (RDI) for nutrients defined as essential by the FDA. The nutrition facts label is mandated to display a Percent Daily Value (%DV) for many nutrients. For protein, a %DV is required if a claim is made for protein, such as "high in protein." The %DV for protein must also be listed on the label if the product is intended for infants and children under 4 years of age. However, if the product is intended for the general population 4 years of age and older and a claim is not made about protein on the label, the %DV is not required for protein. Trans fats and total sugars do not have %DV and must be labeled in grams (g). The standardized footnote on the majority of Nutrition Facts Labels explains how much a nutrient in a serving of food contributes to a typical diet of 2,000 calories per day. The DVs are a population-based nutrient goal to represent the needs of the majority of healthy Americans over the age of 4 years. Manufacturers are not permitted to use other nutrient goals that are established for *age- and gender-specific groups* such as the Estimated Average Requirement (EAR) mentioned below.[7]

Reference Daily Intake (RDI)

The Reference Daily Intake (RDI) is the average daily intake of a particular nutrient (vitamin or mineral) that is likely to meet the nutrient requirements of 97-98 percent of healthy individuals in a particular lifestage or gender group. This value is one of two reference values for reporting nutrients in the nutrition labeling of packaged foods; the other is the Daily Reference Value. RDIs are provided for **vitamins and minerals,** which are essential in human nutrition and established for different populations (adults and children > 4 years of age, children 1 through 3 years, infants through 12 months and pregnant and lactating women). For infants through 12 months, as well as for pregnant and lactating women, there is also an RDI for protein. RDIs for vitamins and minerals are based on a "population-coverage approach," aligning with the highest Recommended Dietary Allowance (RDA) and, where an RDA has not been established, the highest Adequate Intake (AI) of the most recent Institute of Medicine Dietary Reference Intake report.[8]

Daily Reference Value (DRV)

The Daily Reference Value (DRV) is a dietary reference for food labels consistenting of nutrients (except for protein) for which no Recommended Dietary Allowance exists. DRVs have been established **for fat, saturated fat, cholesterol, total carbohydrate, sodium, dietary fiber, protein and added sugars.** DRVs are intended to guide consumers choices relative to intake of energy. The values are based on the Institute of Medicine reports. DRVs have been established for adults and children > 4 years of age, children 1 through 3 years of age, infants through 12 months and pregnant and lactating women. For infants through 12 months, DRVs are only provided for fat and total carbohydrate.[9]

Dietary Reference Intakes (DRI)

The Dietary Reference Intakes (DRI) are set by the Institute of Medicine (IOM) and are recommendations for the amount of nutrients needed each day to maintain health by preventing nutrient deficiencies and reducing risk of disease. DRIs exist for age groups, sex and life stages. The DRIs are made up of four sub-components: Estimated Average Requirement, Recommended Dietary Allowance, Adequate Intake and Tolerable Upper Intake Level.[9]

Estimated Average Requirement (EAR)

The Estimated Average Requirement (EAR) is the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals of a specific age, sex and life stage. The EAR is not useful as an estimate of nutrient adequacy in individuals, because it is a mean requirement for a group, and the variation around this number is considerable. At the EAR, 50% of the individuals in a group are below their requirement, and 50% are above it.[9]

7 FDA. Guidance for Industry: Food Labeling Guide (Appendix F: Calculate the Percent Daily Value for the Appropriate Nutrients). Jan 2013. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

8 Department of Health and Human Services. Food and Drug Administration. Food Labeling: Revision of the Nutrition and Supplement Facts Labels. Docket No. FDA-2012-N-1210. May 2016. https://www.fda.gov/media/134505/download

9 Institute of Medicine of the National Academies. Dietary Reference intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. 2002/2005.

SELECT DEFINITIONS FOR U.S. NUTRIENT GOALS *(CONTINUED)*

Recommended Dietary Allowances (RDA)

The Recommended Dietary Allowance (RDA) is the level of intake of essential nutrients that, on the basis of scientific knowledge, are judged by the Food and Nutrition Board to be adequate to meet the known nutrient needs of practically all healthy persons (97 to 98 percent).[10]

Adequate Intakes (AI)

An Adequate Intake (AI) is established when there is insufficient scientific evidence to determine an RDA. An AI is the recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.[10]

Tolerable Upper Intake Levels (UL)

The Tolerable Upper Intake Level (UL) is the maximum daily intake level level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase.[11]

10 Institute of Medicine of the National Academies. Dietary Reference intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. 2002/2005.

FDA ROUNDING RULES

TABLE 1

Rounding rules for declaring nutrients on the nutrition label or in labeling [11,12,13]

NUTRIENT	INCREMENTAL ROUNDING FOR QUANTITATIVE DECLARATIONS	INSIGNIFICANT AMOUNT[a]	INCREMENTAL ROUNDING FOR % DAILY VALUES
Calories *21 CFR 101.9(c)(1)* Calories from Saturated Fat *21 CFR 101.9(c)(1)(iii)*	< 5 cal - express as 0 ≤ 50 cal - express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment	< 5 cal	No % Daily Value is permitted
Total Fat *(2)* Saturated Fat *(2)(i)* Trans Fat *(2)(ii)* Polyunsaturated Fat *(2)(iii)* Monounsaturated Fat *(2)(iv)*	< 0.5 g - express as 0 < 5 g - express to nearest 0.5g increment ≥ 5 g - express to nearest 1 g increment	< 0.5 g	Nearest 1% increment except for trans fat, polyunsat fat or monounsat fat
Cholesterol *(3)*	< 2 mg - express as 0 2 - 5 mg - express as "less than 5 mg" or "<5 mg" > 5 mg - express to nearest 5 mg increment	< 2 mg	Nearest 1% increment
Sodium *(4)*	< 5 mg - express as 0 5 - 140 mg - express to nearest 5 mg increment > 140 mg - express to nearest 10 mg increment	< 5 mg	Nearest 1% increment
Total Carbohydrate *(6)* Dietary Fiber *(6)(i)*	< 0.5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" or <1 g ≥ 1 g - express to nearest 1 g increment	< 1 g	Nearest 1% increment
Added Sugars *(6)(iii)*	< 0.5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" or <1 g ≥ 1 g - express to nearest 1 g increment	< 0.5 g	Nearest 1% increment
Soluble and Insoluble Fiber; *(6)(i)(A) & (B)* & Total Sugars *(6)(ii)* Sugar Alcohol *(6)(iv)*	< 0.5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" or "< 1 g" ≥ 1 g - express to nearest 1 g increment	< 0.5 g	No % Daily Value is permitted
Protein *(7)*	< 0.5 g - express as 0 0.5 to < 1 g - express as "Contains less than 1 g" or "less than 1 g" or "< 1 g" ≥ 1 g - express to nearest 1 g increment	< 1 g	Nearest 1% increment after adjustment with PDCAAS[b]

11 FDA. Guidance for Industry: Food Labeling Guide (Appendix H: Rounding the Values According to FDA Rounding Rules). Jan 2013. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

12 Department of Health and Human Services. Food and Drug Administration. Food Labeling: Revision of the Nutrition and Supplement Facts Labels. Docket No. FDA-2012-N-1210. May 2016. https://www.federalregister.gov/documents/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-label

13 FDA. Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals. Dec 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-nutrition-and-supplement-facts-labels-questions-and-answers-related-compliance

FDA ROUNDING RULES *(CONTINUED)*

NUTRIENT[14]	INCREMENTAL ROUNDING FOR QUANTITATIVE DECLARATIONS	INSIGNIFICANT AMOUNT[a]	INCREMENTAL ROUNDING FOR % DAILY VALUES
Vitamins (8)		< 2% RDI	<2% of RDI may be expressed as: (1) 2% DV if actual amount is 1% or more (2) 0 (3) An asterisk (*) that refers to statement "*Contains less than 2% of the Daily Value of this (these) nutrient(s)" (4) For Vit. D, calcium, iron and potassium: statement "Not a significant source of (listing the vitamins and minerals omitted)" • 2 to ≤ 10% of RDI – express to nearest 2% DV increment • >10%-50% of RDI- express to nearest 5% DV increment • >50% of RDI – express to nearest 10% DV increment
C	Nearest mg		
E, Niacin, Pantothenic Acid	Nearest 0.1 mg		
Thiamin, Riboflavin, B6	Nearest 0.01 mg		
A	Nearest 10 mcg		
Folate	Nearest 5 mcg		
K	Nearest mcg		
D, B12, Biotin	Nearest 0.1 mcg		
Minerals (8)			
Calcium, Potassium, Phosphorus, Chloride	Nearest 10 mg		
Magnesium	Nearest 5 mg		
Iron, Zinc	Nearest 0.1 mg		
Copper, Manganese	Nearest 0.01 mg		
Iodine, Selenium	Nearest mcg		
Chromium, Molybdenum	Nearest 0.1 mcg		
Essential Nutrient			
Choline	Nearest 10 mg		
Beta-Carotene when a voluntary disclosure appears with Vitamin A	2 to ≤ 10% of RDI for vitamin A- express to nearest 2% DV increment > 10% - 50% of RDI for vitamin A- express to nearest 5% DV increment > 50% of RDI for vitamin A- express to nearest 10% DV increment		(express as % DV)

To express nutrient values to the nearest 1 g increment, for amounts falling exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.99 g), round up (e.g., 3 g). For amounts less than halfway between two whole numbers (e.g., 2.01 g to 2.49 g), round down (e.g., 2 g).

When rounding % DV for nutrients other than vitamins and minerals, when the % DV values fall exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.99), the values round up (e.g., 3 %). For values less than halfway between two whole numbers (e.g., 2.01 to 2.49), the values round down (e.g., 2%).

a. Insignificant Amounts are the values appropriately suitable for the collective phrase "Not a significant source of..."

b. The %DV for protein is voluntary unless a quantitative claim or nutrient content claim is made for the nutrient. The Protein Digestibility Corrected Amino Acid Score (PDCAAS) is a factor that corrects only the %DV based on how digestible the protein source is and how much the amino acid pattern contributes to the growth of a 2-5 year old child. The PDCAAS is defined by regulation. Even if the food is intended for adults, the PDCAAS calculation is based on the amino acid needs of a 2-5 year-old child (21 CFR 101.9).

14 FDA. Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals. Dec 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-nutrition-and-supplement-facts-labels-questions-and-answers-related-compliance

NUTRIENT-BASED CLAIMS FOR DAIRY

Overview of Claims Regulations

This guide discusses the types of food label claims that, when used to highlight the nutritional benefits of food products, must be used in accordance with FDA regulations. These claim categories are:

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

Health Claims

Health claims describe a relationship between a food or food component in reducing the risk of a disease or health-related condition. Only health claims reviewed by and approved by FDA are permitted. This is a lengthy process that requires a considerable amount of supporting scientific evidence. FDA has approved a number of health claims for use on food labels that have significant scientific agreement.[15] These are incorporated into the Code of Federal Regulations (CFR). Examples of approved health claims that certain dairy products may qualify for can be found in the section "Health Claims" in this guide (on page 28). 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. When the science behind a food component and an impact on human disease conditions is not fully supported, the FDA permits a Qualified Health Claim. These pre-approved claims are not incorporated into the CFR; rather, they are communicated on FDA webpages and have strict wording requirements.

Structure/Function Claims

A second category of FDA-regulated food label claims is structure/function claims.[16] These claims provide a unique opportunity to describe the effect a particular nutrient or substance has in maintaining the health/normal structure or function of the body (e.g., calcium helps build strong bones). The subject of the structure-function claim must be the nutrient (i.e., calcium), rather than the food product (i.e., yogurt). Unlike health claims, the FDA does not require conventional food manufactures to notify FDA about their structure/function claims. However, like all other information on a food label, structure/function claims must be truthful and not misleading. The manufacturer must have substantiation that the claim is scientifically "credible and reliable" at the time that the claim is made.

Nutrient Content Claims

A nutrient content claim on a food product characterizes how much of a specific nutrient 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 for a content claim set by the FDA.

Nutrient content claims are allowed for those nutrients for which a Daily Reference Value (DRV) or Reference Daily Intake (RDI) has been established. If an RDI or DRV has not been established, then a manufacturer is limited to a statement of fact as to the level of the nutrient (e.g., 150mg of Omega-3 DHA per serving) as long as such a statement does not implicitly characterize the level of a nutrient and is truthful and not misleading. There are multiple types of nutrient content claims. For more information on these claims see the "Nutrient Content Claims" section in this guide (on page 18). Briefly, here are the types:

- Expressed nutrient content claims
- Relative nutrient content claims
- Implied nutrient content claims

15 21 CFR 101.72-101.83
16 21 CFR 101.93 (f)

USING DAILY VALUES ON THE NUTRITION FACTS LABEL

The Daily Values (DV), which includes Reference Daily Intakes (RDI) and Daily Reference Values (DRVs) are used in food labeling as reference values to facilitate comparisons of the nutritional value of different packaged foods.

Used as "reference values" it is easier for consumers to recognize that 130 mg calcium per serving (10% DV) is a good source of calcium whereas 92 mg of sodium per serving (4% DV) is a relatively low amount of sodium. The footnote of the Nutrition Facts panel states "The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice."[17] For products intended for children (1-3 years of age), the footnote is modified to show 1,000 calories a day (rather than 2,000 calories) because of their lesser calories needs.

Mandatory and voluntary nutrients for nutrition labeling and their DVs are listed in Table 2. The FDA Rounding Rules for declaring nutrients on the nutrition label are illustrated in Table 1.

17 Department of Health and Human Services. Food and Drug Administration. Food Labeling: Revision of the Nutrition and Supplement Facts Labels. Docket No. FDA-2012-N-1210. May 2016. https://www.federalregister.gov/documents/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels

USING DAILY VALUES ON THE NUTRITION FACTS LABEL *(CONTINUED)*

TABLE 2

Nutrient and Daily Values (as RDI or DRVs) used on the nutrition facts label (adults and children ≥4 years)

NUTRIENT	UNIT OF MEASURE	RDI OR DRVS[a,b]
Total Fat	grams (g)	78 (DRV)
Saturated fat	grams (g)	20 (DRV)
Trans fat	grams (g)	(no DV)
Polyunsaturated fat (Voluntary[c])	grams (g)	(no DV)
Monounsaturated fat (Voluntary[c])	grams (g)	(no DV)
Cholesterol	milligrams (mg)	300 (DRV)
Sodium	milligrams (mg)	2,300 (DRV)
Fluoride (voluntary)	milligrams (mg)	(no DV)
Total Carbohydrate	grams (g)	275 (DRV)
Dietary Fiber	grams (g)	28 (DRV)
Soluble Fiber (Voluntary)	grams (g)	(no DV)
Insoluble Fiber (Voluntary)	grams (g)	(no DV)
Total Sugars	grams (g)	(no DV)
Added Sugars	grams (g)	50 (DRV)
Sugar alcohols (Voluntary)	grams (g)	(no DV)
Protein	grams (g)	50 (DRV)
Vitamin D	micrograms (mcg)	20
Calcium	milligrams (mg)	1,300
Iron	milligrams (mg)	18
Potassium	milligrams (mg)	4,700
Vitamin A (Voluntary)	Micrograms Retinol Activity Equivalents (mcg RAE[20])	900
Vitamin C (Voluntary)	milligrams (mg)	90
Vitamin E (Voluntary)	milligrams (mg)[18]	15
Vitamin K (Voluntary)	micrograms (mcg)	120
Thiamin (Voluntary)	milligrams (mg)	1.2
Riboflavin (Voluntary)	milligrams (mg)	1.3
Niacin (Voluntary)	milligrams Niacin Equivalents (mg)	16
Vitamin B6 (Voluntary)	milligrams (mg)	1.7
Folate (Voluntary)	micrograms Dietary Folate Equivalents (mcg DFE[19])	400
Vitamin B12 (Voluntary)	micrograms (mcg)	2.4
Biotin (Voluntary)	micrograms (mcg)	30
Pantothenic Acid (Voluntary)	milligrams (mg)	5
Phosphorus (Voluntary)	milligrams (mg)	1,250
Iodine (Voluntary)	micrograms (mcg)	150
Magnesium (Voluntary)	milligrams (mg)	420
Zinc (Voluntary)	milligrams (mg)	11
Selenium (Voluntary)	micrograms (mcg)	55
Copper (Voluntary)	milligrams (mg)	0.9
Manganese (Voluntary)	milligrams (mg)	2.3
Chromium (Voluntary)	micrograms (mcg)	35
Molybdenum (Voluntary)	micrograms (mcg)	45
Chloride (Voluntary)	milligrams (mg)	2,300
Choline (Voluntary)	milligrams (mg)	550

a. Nutrients in this table are listed in the order specified by regulations on a food label in accordance with FDA: Final Rule. *Food Labeling: Revision of the Nutrition and Supplement Facts Labels.* May 2016. FDA–2012–N–1210. This list includes nutrients and values for packaged foods intended for adults and children 4 years of age and older. Regulations establish different declarations for nutrients and values when labeled foods are intended for infants (12 months and under), children (1-3 years of age) and pregnant or lactating women. A few mandatory nutrient names and the respective %Daily Values are required to display text as bold-faced font styles: total fat, cholesterol, sodium, total carbohydrate and protein.

b. Based on intake of 2,000 calories daily.

c. Voluntary declarations for polyunsaturated fat and monounsaturated fat, unless a claim is made for fatty acids or cholesterol (e.g., ow saturated fat, 0g trans fat, omega-3 fatty acids). See 21 CFR 101.9(c)(2)(iii) and (iv).

18 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.

19 DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg folic acid

20 RAE = Retinol Activity Equivalents; 1 microgram RAE = 1 microgram retinol, 2 microgram supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms β-carotene, or 24 micrograms β-cryptoxanthin.

REFERENCE AMOUNTS CUSTOMARILY CONSUMED (RACC) AND LABELED SERVING SIZE

For the purpose of nutrition labeling (e.g. the Nutrition Facts) and making product claims, nutrient amounts are declared for one serving of the food based on a pre-determined quantity of food set by FDA regulations (section 403(q)(1)(A)(i) of the FD&C Act). The serving size labeled on the Nutrition Facts is based on a standardized **Reference Amount Customarily Consumed (RACC)** for that food category. The FDA used national food consumption survey data for Americans 4 years and older to define the RACCs. RACC's are not *recommended* serving sizes, but rather by law, RACCs must be based on how much food people *actually* consume. The RACCs and nutrient regulations were updated on May 27, 2016. The quantities for some but not all food categories were adjusted to represent the latest survey data.[21]

When updating the Nutrition Facts formats and nutrient declarations, manufacturers must also consider that a change in RACC will affect the servings per container and possibly nutrient content claims. Notably, the most recent 2016 regulatory update also mandates when the Nutrition Facts must be displayed per labeled serving and per container if the contents of the package are 200-300% of the RACCs. Manufacturers must implement a comprehensive change to the Nutrition Facts Label and may not arbitrarily choose to use prior RACCs. Manufacturers may also petition FDA to consider alternative RACCs if their products do not conform to the existing product categories.

The labeled serving size will be close but may not be exactly the same as the reference amount. This is because the regulations dictate that the labeled serving size be represented in consumer-friendly measurements that are available in a common household measures, such as cups, tablespoon, teaspoon, piece, slice, fraction, ounce, fluid ounce or other common household equipment used to package food products. This household measurement is then followed by a metric unit of measure (that will also be the basis for FDA enforcement of the nutrient declared values). If a household measure is not conveniently represented by a common fraction (such as ½, ⅔, or ¼), then ounces may be used for the labeled serving size. When products are pre-cut or pre-sliced or individually wrapped, these discrete units are considered the household unit. Manufacturers must declare the number of discrete units closest to the RACC (followed by the metric unit declaration) as the labeled serving size.[22]

The consistent use of serving sizes for products in a similar category allows product claims to be evaluated fairly by consumers and regulatory agencies. In addition to on-pack labeled serving sizes, most food label claims must be based on the RACC (i.e. *High/Excellent Source* is defined as at least 20% of the RDI or DRV per RACC). In some cases, foods with a small RACC (less than or equal to either 30 g or 2 tablespoons (30 mL)) must meet the requirements of a claim based on 50 grams of the product, rather than per RACC. For dairy, this impacts some cheese products. Some nutrient content claims (e.g. *Fat Free*) require a food to meet the claim criteria both on a per RACC and a per labeled serving basis.

21 In a final rule published in the Federal Register of May 27, 2016, "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Minds; and Technical Amendments" (81 FR 34000; "2016 final rule"), FDA amended 21 CFR 101.12(b) to update or modify certain pre-existing RACCs, and to establish RACCs for new product categories. FDA has published guidance for industry including examples of the newest RACCs with suggested household measures and product-relevant examples. The most recent February 2018 update is here: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm535368.htm.

22 21 CFR 101.9

REFERENCE AMOUNTS CUSTOMARILY CONSUMED (RACC) AND LABELED SERVING SIZE *(CONTINUED)*

TABLE 3

Reference Amounts Customarily Consumed (RACC) for various dairy products[23]

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)[a,b]	SUGGESTED LABELED SERVING SIZE STATEMENT EXAMPLES[a,c]	EXAMPLES OF PRODUCTS[d]
Milk and milk-based drinks	240 mL	1 cup (240mL) 8 fl oz (240 mL)	All milk, regular and flavored (e.g., chocolate milk) of any fat content; all milk-based meal replacements (e.g., nutritional shakes); all hot cocoa; malted milk beverages, and all other milk-based beverages (e.g., breakfast drink) with the exception of milkshakes. NOTE: Milk-based beverages mean that milk and milk-derived ingredients are the major ingredient of the beverage when prepared for consumption. For example, a dry beverage mix product may not contain milk or milk-derived ingredients. However, if the package direction recommends adding milk to make the beverage for consumption, the product is classified as a milk-based beverage.
Cheese (all others except those listed as separate categories. This category includes cream cheese and cheese spread)	30 g	1 oz (28 g) for bulk 1 slice (21 g) for distinct pieces 1 tbsp (28 g) for cream cheese and cheese spreads	All natural and processed cheese products (including cheese whiz) other than cottage cheese, ricotta cheese, and grated hard cheese (e.g., Brie, cheddar, Colby, mozzarella, muenster). NOTE: Cheese sauce belongs to the "Minor main entrée sauce (e.g., pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce" product category.
Cottage cheese	110 g	½ cup (124 g)	All non-dry cottage cheese (regular, low-fat, or fat-free) with or without fruits. NOTE: Dry cottage cheese belongs in the "Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese" product category.
Cheese used primarily as ingredients (e.g., dry cottage cheese and ricotta cheese)	55 g	¼ cup (62 g)	All dry cottage cheese and ricotta cheese.
Cheese, grated hard (e.g., Parmesan and Romano)	5 g	1 tbsp (5 g)	All hard grated cheese included grated Parmesan and Romano cheese.
Custard or Pudding	½ cup prepared; amount to make ½ prepared when dry	1 Pudding cup (92 g) ½ cup (118 g) 1 Packet (23 g)	All types of custards, mousse, and puddings (flavored and unflavored). All dry mixes with various flavor used to make custards or pudding. NOTE: Frozen custards and puddings belong to the product category "Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups)."
Yogurt	170 g	¾ cup (183 g) 1 Container (170 g)	All forms of yogurts: drinkable, not-drinkable, plain, flavored, and sweetened with or without fruit, nuts, and other ingredients (e.g., granola) packaged together or in separate compartments that are mixed together for consumption.

23 FDA. Final Rule. Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates. May 2018. FDA-2004-N-0258-0136

REFERENCE AMOUNTS CUSTOMARILY CONSUMED (RACC) AND LABELED SERVING SIZE *(CONTINUED)*

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)[a,b]	SUGGESTED LABELED SERVING SIZE STATEMENT EXAMPLES[a,c]	EXAMPLES OF PRODUCTS[d]
Sour Cream	30 g	2 tbsps (30 g)	All types of sour cream with all types of fat content.
Butter	1 tbsp	1 tbsp (14 g)	All types of butter and margarine spreads (regular, diet, lite/light, liquid, and whipped); oils; and shortenings.
Ice Cream and Frozen yogurt	2/3 cups (this includes the volume for coatings and wafers)	⅔ cup (90 g) 1 bar (89 g) for individually wrapped/ packaged	All types of bulk and novelties (e.g., bars, sandwiches, cups, slices, cones, pops) ice cream, frozen yogurt, sherbet, sorbet, frozen custard, and other milk-based frozen desserts; frozen or unfrozen flavored and/or sweetened ice and pops (e.g., popsicles, flavored ice, snow cones); frozen fruit juices and fruit juice novelties, all flavored, with or without fruits or nuts.

a. The labeled serving size for dehydrated products (that require reconstitution) or mixes that require further preparation, is the amount of a powdered or dried product necessary to prepare the ready-to-eat RACC.
b. These are the RACCs for products intended to serve adults and children (4 years of age and older) or pregnant and lactating women. Different RACCs are established for foods intended for infants (through 12 months of age) or children (1-3 years of age).
c. The labeled serving size must be listed in both common household measures (cup, tablespoon, piece, slice, etc.) followed by the metric units of measure. 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 RACC.
d. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. Reference Amounts Customarily Consumed: List of Products for Each Product Category: Guidance for Industry. February 2018. https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535370.pdf

DISCLOSURE STATEMENTS AND DISQUALIFYING LEVELS[24]

FDA expects messages about specific foods to be presented in the context of a balanced dietary intake. A threshold for nutrients of public health concern has been established for those nutrients connected with chronic health risks. Exceeding one or more of these nutrient levels disqualifies a food from most FDA-approved health claims (although there are some exceptions). For more information, see the section below, "Health Claims" and "Qualified Health Claims."

If a food bearing a nutrient content claim exceeds the threshold levels of any of the nutrients listed in Table 4 per RACC and per labeled serving size, then the nutrient content claim must be followed by a disclosure statement that reads: See *nutrition information for [nutrient requiring disclosure] content.* The disclosure statement must appear prominently and in immediate proximity to the claim with no intervening material. The font size of the disclosure text is not smaller than ½ the font size of the primary claim. 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.

When the RACC is 30 grams or less, the disclosure level is based on 50 grams. This is often the reason that calcium content claims on hard cheeses are accompanied by the phrase: See nutrition facts for saturated fat and sodium content.

For dehydrated products (that require reconstitution) or mixes that require further preparation, the amount of a powdered or dried product necessary to prepare the ready-to-eat RACC is the labeled serving size.

TABLE 4

Disclosure nutrients and disqualifying nutrient level[25]

DISCLOSURE/ DISQUALIFYING NUTRIENTS[a]	DISCLOSURE/DISQUALIFYING LEVEL PER RACC AND PER LABELED SERVING SIZE[b]
Total fat	13 g
Saturated fat	4 g
Cholesterol	60 mg
Sodium	480 mg

a. These disclosure/disqualifying nutrient levels apply to individual foods; the levels are different for meal and main dish products.
b. If the RACC is small (30 grams or 2 Tablespoons or less), then the claim must also comply with these nutrient levels on a 50 gram basis.

24 As FDA is evaluating the nutrient-related regulations concerning Healthy (April 2017), it is possible the Agency may change the regulations concerning disqualifying and disclosure nutrients
25 21 CFR 101.13(h) and 21 CFR 101.14(a)(4).

ABBREVIATIONS PERMITTED BY REGULATION

For labels with less than 40 total square inches of available space, the following abbreviations are allowed (21 CFR 101.9).

Serving size—Serv size

Servings per container—Servings

Calories from saturated fat—Sat fatcal

Calories from fat—Fat cal

Saturated fat—Sat fat

Monounsaturated fat—Monounsat fat

Polyunsaturated fat—Polyunsat fat

Cholesterol—Cholest

Total carbohydrate—Total carb.
This abbreviation can also be used on dual-column displays as shown in 21 CFR 101.9

Dietary fiber—Fiber

Soluble fiber—Sol fiber

Insoluble fiber—Insol fiber

Sugar alcohol—Sugar alc

Other carbohydrate—Other carb

Vitamin—Vit

Potassium—Potas

Includes—Incl.
This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

NUTRIENT CONTENT CLAIMS

Nutrient content claims are label statements that characterize the amount of a nutrient in a food, either expressed, relative or implied. Nutrient content claims can highlight a product's strongest nutrition selling points. Many dairy products are excellent or good sources of several vitamins and minerals, including calcium, phosphorus, pantothenic acid (vitamin B5), riboflavin (vitamin B2), vitamin B12, vitamins A and D and protein. Unlike many other food choices, dairy products deliver substantial nutritional value. The FDA's nutrient content claim regulations provide many opportunities that allow food labels to communicate a particular nutritional value contained in dairy products. Remember to include nutrient disclosures adjacent to the nutrient content claims when applicable.

Key Points When Making Nutrient Content Claims

- Nutrient content claims must be met on both RACC and labeled serving size. High levels of certain nutrients must be disclosed (see "Disclosure Statement Disclosure Statements and Disqualifying Levels" on page 16).
- When a disclosure statement is required, it must be placed close to the nutrient content claim.
- The type size used for nutrient content claims may not be larger than twice that of the product name (statement of identity).
- The %DV for protein must be adjusted based on PDCAAS (Protein Digestibility Corrected Amino Acid Score) in order to make a nutrient content claim for protein.
- Relative nutrient content claims (e.g. more, less) must be accompanied by comparative information about both the labeled food and the reference food.
- Relative nutrient content claims about added nutrients can only be used if the fortification is in accordance with the FDA Fortification Policy.
- With some exceptions,[26] nutrient content claims are generally not allowed on food intended for use by infants or children younger than two years of age.
- FDA regulations regarding nutrient content claims apply to spelling variations and synonyms (e.g., lo is equivalent to low, *high in* is equivalent to *excellent source*).

26 21 CFR 101.13(b)(3)

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

Expressed Nutrient Content Claims

An expressed nutrient content claim[27] is any direct statement about the absolute level or range of a nutrient in the food (e.g., *Low sodium, Contains 100 calories, High in calcium or Milk is good/excellent source of 13 essential nutrients*). Expressed nutrient content claims can only be made for those nutrients with established Reference Daily Intakes (RDI) or Daily Reference Values (DRV), and only when they are approved by a specific nutrient content claim regulation. These types of claims are based on per RACC criterion (even if the RACC is small) and per labeled serving size.[28] When a product displays a dual column Nutrition Facts label (per serving and per container), it is important that the serving size be included adjacent to the nutrient content claims for greater customer understanding.

Expressed nutrient content claims refer to a specific nutrient level in a single food. These types of claims, like high in calcium or low in fat do not make comparisons to any other food. The meaning of the descriptive terms used in absolute claims (e.g., free, low, very low (sodium only), high, good source) are defined in FDA's nutrient content claim regulations. Also common are claims referring to "percentage" or "amount."

- *Excellent Source*[29]*:* If the product contains 20% or more of the RDI or DRV per RACC for that nutrient.
- *Good Source*[30]*:* If the product contains 10% to 19% of the RDI or DRV per RACC for that nutrient.
- *Supplies ____% of the DV of per serving (or per bottle or per container).*

Also, keep in mind there are allowable synonyms for these claims which help provide some creative leeway.

- *Excellent Source = high = rich in = packed with*
- *Good Source = contains = provides = with*

See Tables 5.1 and 5.2 at the end of this Nutrient Content Claims section for examples of expressed nutrient content claims for select dairy products.

Numeric Declaration Nutrient Content Claims

The FDA permits the use of factual quantitative statements that disclose the amount of a nutrient in a product (e.g., 100 calories or 5 g of fat) provided that such a statement does not implicitly characterize the level of a nutrient and is not false or misleading. This provision was intended as a way for manufacturers to present quantitative information about nutrients that do not have established RDI or DRV's. For example, there is no established DRV for lactose.

A statement about a nutrient *amount* or *percentage* that implicitly characterizes the level of the nutrient is permitted if the food either qualifies for the implied claim or the statement accompanied by a disclaimer that the food is not *low* or a *good source* (as appropriate) of that nutrient.

27 21 CFR 101.13(b)(1)
28 21 CFR 101.54(e)
29 21 CFR 101.54(b)
30 21 CFR 101.54(c)

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

Relative Nutrient Content Claims

A relative nutrient content claim is one that describes the level of a nutrient in one food compared to the level in another food, such as *50% less fat than regular cheese.* Descriptor terms that are defined by regulation and frequently used as relative claims are: *light, lite, reduced, less* or *more.* A relative claim for decreased levels of a nutrient may not be made if the nutrient content of the reference food meets the requirement for a *low* claim for that nutrient (e.g., 3 g fat or less).[31]

In *light* and *reduced* claims, the comparison must be for similar foods; for example, reduced-fat Swiss cheese would be compared with regular Swiss cheese, or lite cream cheese with regular cream cheese. Additionally, for a *light* claim, the reference food can only be the marketplace norm or from a national nutrient database for that food and cannot be from a single product, such as a company's regular product. Monitor the marketplace yearly to ensure that reference (comparison) products are still in commerce across a region or nationally.

For relative nutrient content claims other than *light*, including *less* and *more* claims, the reference food may be the same as that provided for *light* or it may be the manufacturer's regular product. For the *more* and *less* claims, the comparison may be between either similar foods or dissimilar foods within the same product category (e.g., potato chips and pretzels are dissimilar foods but are both snacks). The nutrient levels used for the reference or 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.

The following two comparative statements must accompany all relative claims:

- Identity of the reference food and the percentage (or fraction) of nutrient difference between the product and the reference food (e.g., *50% less fat than [reference food]*, or *1/3 fewer calories than [reference food]*) must appear on the principal display panel adjacent to the relative claim.
- Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving (and per RACC if different from the serving size) with that in the reference food may appear on either the principal display panel or the information panel (e.g., *fat content has been reduced from ____g to ____g per serving*). Include the household measurement or metric weight of the serving to avoid misleading representations.

More Claims[32]

Claims with descriptive terms such as *more, fortified, enriched, added, extra* and *plus* are relative claims that may be used to describe the level of protein, vitamins, minerals (other than sodium) or dietary fiber present in an individual food. Foods using these claims must contain at least 10% more of the RDI or DRV of the nutrient per serving size and per RACC than is found in an appropriate reference (comparison) food. For *fortified, enriched* or *added,* the reference food must be a similar food (e.g., enriched yogurt compared with regular yogurt). For *more* claims, the reference food may be a dissimilar food in the same category based on the typical eating occasion (e.g., milk with more calcium compared with orange juice).

Because these are relative claims, they must be accompanied with information about the percentage (or fractional) nutrient amount difference from the comparison food, and the levels of the nutrient in both foods. For example: *Contains twice the calcium as regular cottage cheese* would be accompanied with *contains 170 mg calcium per serving, which is 10% more of the DV for calcium, compared to 70 mg per serving in regular cottage cheese.* If the *more* claim refers to a nutrient that has been added to the food, adding the nutrient must be in accordance with FDA's Fortification Policy.[33] The Fortification Policy establishes a uniform set of principles for the rational addition of nutrients to foods. Also see Nutrient Fortification: General and Dairy Specific section within Regulatory Concepts and Definitions for Dairy on page 43. The incremental difference must be 10% DV or more per RACC.

31 21 CFR 101.13(j)(3)
32 21 CFR 101.54 (e)
33 21 CFR 104.20

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

Reduced Claims

Dairy products can be modified to reduce the amount of certain components such as total fat, saturated fat, sodium, cholesterol, total sugar[34] or calories to meet consumer needs and preferences. This can provide a marketing opportunity for *reduced* claims.

FDA regulations provide certain descriptors such as *free*, *reduced* and *low* (*very low* is for sodium only) for nutrient content claims to describe the nutritionally modified product. Calories,[35] Total Fat,[36] Saturated Fat,[37] Cholesterol,[38] Sodium,[39] and Sugar[40] all have their own definitions and criteria that must be met in order to use these terms.

In general, to use a *reduced* claim, there must be at least a 25% reduction per RACC and serving size for the nutrient. *Less* and *lower* may be used as synonyms for *reduced*. When making a reduced nutrient content claim about calories, *fewer* may be used as a synonym instead of less.[41] *Reduced* claims are required to be accompanied by the same comparative information of other relative claims. For example, a lower fat Swiss cheese might be labeled as: *Reduced Fat Swiss Cheese. 37% less fat than our regular Swiss Cheese. Reduced fat Swiss 5g fat per serving, regular Swiss cheese 8g fat per serving.*

Light or Lite Claims

Light claims are also relative 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 in Table 19 of the Appendix.

Implied Nutrient Content Claims

Implied nutrient content claims[42] describe the food or ingredient in a manner that suggest that a nutrient is absent or present in a certain amount (e.g., *High in oat bran* implies the food is a good source of dietary fiber); or suggest that the food, because of its nutrient content, may be useful in maintaining nutritious dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., *Healthy*[43]). Use of the term "only" adjacent to a quantitative claim is also regulated as an implied nutrient content claim. Therefore, to avoid being misleading to consumers, the claim must be qualified with text (e.g., *"only 5 grams of carbs per serving—not a low-calorie food"*) that puts the claim in context.

Implied nutrient content claims may be used on food labels provided the food meets the regulatory criteria established for the claim that is implied. The FDA will determine on a case-by-case basis whether a product label bears an implied nutrient content claim. The FDA has identified some statements that are considered implied nutrient content claims:

Examples of Label Statements That Are Implied Claims

The FDA has identified the following types of statements as being implied nutrient content claims:

- A claim that suggests a nutrient is absent or present in a certain amount is an implied nutrient content claim (e.g., *high in oat bran* is a claim about an ingredient that implies the food is high in dietary fiber).
- A product name that includes the name of a characterizing ingredient associated with a nutritional benefit is an implied nutrient content claim. For example, using oat bran in the name of a food, e.g., *oat bran muffins*, implies that the food is a good source of dietary fiber.
- A phrase like, *as much [nutrient] as a [food]*, is an implied nutrient content claim. The *as much as*-type implied claims may be used provided both the labeled food and the comparison (reference) food qualify as a good source of the nutrient. The quantitative value of the nutrient per serving may also appear to reinforce relative or comparative nature of the food (when the nutrient quantities do not appear within the Nutrition Facts label).

34 FDA has not issued regulations for reduced added sugars. Until formalized by regulation, the claim is not permitted.
35 21 CFR 101.6 (b)
36 21 CFR 101.62 (b)
37 21 CFR 101.62 (c)
38 21 CFR 101.62 (d)
39 21 CFR 101.61
40 21 CFR 101.6 (c)
41 21 CFR 101.60 (b) (4)
42 21 CFR 101.13 (b)(2)
43 FDA Guidance. Use of the Term "Healthy" in the Labeling of Human Food Products: Guidance for Industry. September 2016

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

Healthy

Healthy and all variations of the word *health* is a specific FDA-defined implied nutrient content claim. Under its current definition, *healthy* implies that a food does not contain any "unhealthy" levels of nutrients. Per the current definition and the September 2016 FDA-released guidance[44], any product using the implied nutrient content claim *healthy* (and all variations of the word *health*) must meet the defined criteria. See Table 20 of the Appendix for additional details, definitions and examples of selected dairy products that qualify. On September 29th, 2022, the FDA issued a proposed rule to update the definition for the implied nutrient content claim *healthy* to be consistent with current nutrition science and Federal dietary guidance, especially the Dietary Guidelines for Americans, regarding how consumers can maintain healthy dietary practices. No additional updates were available as of November 2022.

Examples of Nutrient Content Claims for Select Dairy Products

Tables 5.1 and 5.2 outline examples of dairy products that may qualify for excellent or good source claims based on the 2016 regulatory update. Additional examples of nutrient content claims can be found in Tables 14-21 of the Appendix, and further nutritional information can be found in Table 22.

TABLE 5.1
Examples of dairy products that may qualify for *excellent* or *good source* claims

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)	*EXCELLENT SOURCE*[a] *HIGH RICH IN*	*GOOD SOURCE*[b] *PROVIDES CONTAINS*
Fluid Milk			
Milk, plain, vitamin D fortified (all fat levels)[c]	240 mL	Calcium Phosphorus Riboflavin Vitamin B12 Pantothenic Acid Iodine	Protein Vitamin D Vitamin A Niacin Zinc Selenium Potassium[d]
Flavored milk, vitamin D fortified (all fat levels)[e]	240 mL	Calcium Phosphorus Riboflavin Vitamin B12 Pantothenic Acid Iodine	Protein Vitamin D Vitamin A Niacin Zinc Selenium Potassium[d]

44 FDA Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products. September 2016

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)	*EXCELLENT SOURCE[a] HIGH RICH IN*	*GOOD SOURCE[b] PROVIDES CONTAINS*
Yogurt[f]			
Traditional, unflavored	170 grams	Calcium Riboflavin Vitamin B12 Phosphorus Pantothenic Acid Iodine[g]	Protein Selenium Zinc Potassium[d]
Traditional, flavored	170 grams	Calcium Riboflavin Vitamin B12 Iodine[g]	Protein Selenium Phosphorus Zinc Pantothenic Acid Potassium[d]
Greek, unflavored	170 grams	Protein Selenium Riboflavin Vitamin B12 Phosphorus Iodine[g]	Calcium Pantothenic Acid
Greek, flavored	170 grams	Protein Selenium Riboflavin Vitamin B12 Iodine[g]	Calcium Phosphorus Pantothenic Acid

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)	*EXCELLENT SOURCE*[a] *HIGH RICH IN*	*GOOD SOURCE*[b] *PROVIDES CONTAINS*
Cheese[f]			
Hard Cheese (Parmesan)	Grated: 5 grams Other: 30 grams		Protein Calcium Phosphorus Niacin[h] Iodine[g]
Pasta Filata (Mozzarella, Provolone)	30 grams		Protein Calcium Phosphorus Selenium Vitamin B12 Iodine[g] Niacin[h]
Processed (American, Blends)	30 grams	Calcium	Protein Phosphorus Vitamin B12 Iodine[g] Niacin[h]
Semi-hard (Cheddar, Gouda, Swiss)	30 grams	Calcium	Protein Phosphorus Selenium Vitamin B12 Iodine[g] Niacin[h]
Semi-soft (Goat, Monterey, Mexican Blend)	30 grams		Protein Calcium Phosphorus Vitamin B12 Iodine[g] Niacin[h]
Soft-fresh (Cottage, Ricotta)	Cottage: 110 grams Ricotta: 55 grams	Protein Vitamin B12 Iodine[g]	Phosphorus Selenium Riboflavin Niacin[h]

This information is based on nutrient amounts per RACC after FDA rounding rules (see Table 1).

a. Contains 20% or more of the RDI or DRV per RACC.

b. Contains 10-19% of the RDI or DRV per RACC.

c. Source for milk: USDA FoodData Central online at https://fdc.nal.usda.gov/. Mean values calculated from database entries across all fat levels of plain vitamin D-fortified fluid milk in Legacy, Foundation, and Survey (FNDDS) data sources (n = 12).

d. FDA's Daily Value (DV) for potassium (4700 mg) is based on a 2005 DRI recommendation. In 2019, NASEM updated the DRI to 3400 mg. These calculations are based on the 2019 DRI (3400 mg). FDA rule-making is needed to update this value for the purpose of food labeling.

e. Flavored milk contains the same 13 nutrients found in non-flavored milk (a separate analysis for flavored milk was not conducted due to insufficient FoodData Central entries).

f. Source for yogurt and cheese: USDA FoodData Central online at https://fdc.nal.usda.gov/. Mean values calculated from database entries across all fat levels in Legacy, Foundation, and Survey (FNDDS) data sources for the top 85% of segment shares for 2021 (yogurt: n = 36; cheese: n = 91).

g. Source: USDA, FDA and ODS-NIH Database for the Iodine Content of Common Foods (2022). https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/methods-and-application-of-food-composition-laboratory/mafcl-site-pages/iodine/

h. Niacin values calculated from USDA FoodData Central foods that contain tryptophan values.

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

TABLE 5.2

Examples of dairy products that may qualify for *excellent* or *good source* claims

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)	*HIGH*[a] *EXCELLENT SOURCE RICH IN*	*GOOD SOURCE*[b] *PROVIDES CONTAINS*
Cheese			
Pasteurized process American cheese (vitamin D fortified)	30 g	Calcium	Protein Phosphorus Vitamin A Vitamin D Vitamin B12
Blue	30 g		Calcium Pantothenic Acid (Vit B5) Vitamin B12 Protein Some Blue cheese may be a good source of Phosphorus.[c] Each product should be evaluated separately.
Brick	30 g		Calcium Phosphorus Protein Vitamin B12 Some Brick cheese may be a good source of Vitamin A.[c] Each product should be evaluated separately.
Brie	30 g	Vitamin B12	Protein Riboflavin
Camembert	30 g		Protein Vitamin B12 Riboflavin Niacin
Cheddar	30 g		Phosphorus Protein Calcium Vitamin B12 Vitamin A Some Cheddar cheese may be a good source of Zinc and/or Riboflavin.[c] Each product should be evaluated separately.
Cheddar, reduced fat	30 g	Selenium	Phosphorus Protein Zinc Calcium Vitamin B12 Some reduced-fat Cheddar cheese may be a good source of Riboflavin.[c] Each product should be evaluated separately.
Low fat, Cheddar or Colby	30 g		Phosphorus Protein Some low-fat Cheddar or Colby cheese may be a good source of Calcium.[c] Each product should be evaluated separately.
Cheddar, nonfat or fat free	30 g	Calcium	Phosphorus Protein

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)	*HIGH*[a] *EXCELLENT SOURCE RICH IN*	*GOOD SOURCE*[b] *PROVIDES CONTAINS*
Cheese			
Colby	30 g		Phosphorus Protein Calcium Vitamin B12 Some Colby cheese may be a good source of Niacin.[c] Each product should be evaluated separately.
Cream cheese	30 g		Vitamin A
Edam	30 g		Phosphorus Protein Calcium Zinc Vitamin B12 Some Edam cheese may be a good source of Riboflavin.[c] Each product should be evaluated separately.
Feta	30 g	Vitamin B12	Calcium Riboflavin
Gouda	30 g		Phosphorus Protein Calcium Zinc Vitamin B12
Monterey	30 g		Phosphorus Protein Calcium Vitamin B12 Some Monterey cheese may be a good source of Riboflavin.[c] Each product should be evaluated separately.
Mozzarella, whole milk	30 g	Vitamin B12	Protein Calcium
Mozzarella, low moisture, part skim	30 g	Vitamin B12	Phosphorus Protein Calcium Some Mozzarella cheese may be a good source of Zinc.[c] Each product should be evaluated separately.
Mozzarella, nonfat	30 g	Calcium	Protein Vitamin B12 Phosphorus Zinc
Muenster	30 g		Phosphorus Protein Calcium Vitamin B12 Some Muenster cheese may be a good source of Vitamin A.[c] Each product should be evaluated separately.

NUTRIENT CONTENT CLAIMS *(CONTINUED)*

PRODUCT	REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC)	*HIGH*[a] *EXCELLENT SOURCE RICH IN*	*GOOD SOURCE*[b] *PROVIDES CONTAINS*
Cheese			
Provolone	30 g		Phosphorus Protein Calcium Vitamin B12
Swiss	30 g	Calcium Vitamin B12	Phosphorus Protein Zinc Some Swiss cheese may be a good source of Vitamin A.[c] Each product should be evaluated separately.
Swiss, low fat	30 g	Calcium Vitamin B12	Phosphorus Protein Zinc
Swiss, nonfat or fat free	30 g	Calcium Vitamin B12	Phosphorus Protein Zinc
Ricotta, whole milk	55 g		
Ricotta, part skim milk	55 g		Protein Calcium

This information is based on nutrient amounts per RACC after FDA rounding rules (see Table 1).

a. Contains 20% or more of the RDI or DRV per RACC.
b. Contains 10-19% of the RDI or DRV per RACC.
c. Source for milk: USDA FoodData Central online at https://fdc.nal.usda.gov/. Mean values calculated from database entries across all fat levels of plain vitamin D-fortified fluid milk in Legacy, Foundation, and Survey (FNDDS) data sources (n = 12).
d. FDA's Daily Value (DV) for potassium (4700 mg) is based on a 2005 DRI recommendation. In 2019, NASEM updated the DRI to 3400 mg. These calculations are based on the 2019 DRI (3400 mg). FDA rule-making is needed to update this value for the purpose of food labeling.
e. Flavored milk contains the same 13 nutrients found in non-flavored milk (a separate analysis for flavored milk was not conducted due to insufficient FoodData Central entries).
f. Source for yogurt and cheese: USDA FoodData Central online at https://fdc.nal.usda.gov/. Mean values calculated from database entries across all fat levels in Legacy, Foundation, and Survey (FNDDS) data sources for the top 85% of segment shares for 2021 (yogurt: n = 36; cheese: n = 91).
g. Source: USDA, FDA and ODS-NIH Database for the Iodine Content of Common Foods (2022). https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/methods-and-application-of-food-composition-laboratory/mafcl-site-pages/iodine/
h. Niacin values calculated from USDA FoodData Central foods that contain tryptophan values.

HEALTH CLAIMS

Overview/Definitions

A health claim,[45] 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. These claims are not regulated the same as when the term healthy is applied to a product label; *healthy* is an implied nutrient content claim with different regulatory criteria (see page 22).

There are three regulatory pathways through which new health claims become approved for use on food or dietary supplement labels. Each of the pathways begins with a company or citizen petition to the FDA to consider the publicly available reports on the food, the food substance and the impact of risk for disease or health-related condition. Once the FDA approves the health claim language, then any company that complies with the criteria may use the language in the claim. The list of pre-approved health claims changes and manufacturers are encouraged to review the terms and nutrient criteria yearly.

- The 1990 Nutrition Labeling and Education Act[46] (NLEA) allows the FDA to issue authorizing regulations for individual health claims for foods and dietary supplements after the FDA reviews the scientific evidence and concludes there is **significant scientific agreement** (SSA) that the substance/disease relationship is supported by the totality of available scientific evidence.
- The 1997 Food and Drug Administration Modernization Act[47] (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). These **authoritative statement health claims** 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," meet all other existing FDA requirements for health claims and meet any specific criteria included in the claim notification. These claims may be used on food labels beginning at 120 days after FDA receives a notification of the claim. FDA will inform the submitter by letter as soon as possible within the 120 days when the notification does not comply with the requirements for a FDAMA notification. When a notification does not meet the requirements, the use of the claim is not authorized under FDAMA.
- 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 a health claim-authorizing regulation.

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. It could make the marketing text a drug 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 not considered to be health claims, provided that the context of the statement does not suggest that a specific substance is the subject of the statement. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are regulated as structure/function claims rather than as health claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health-related condition. Only the health claims are subject to FDA review and authorization.

The FDA has approved a number of health claims — by regulation (21 CFR 101.72 through 101.83), or as Qualified Health Claims, or through FDAMA authoritative statement-based claim notifications — that can be used on food products.[48] The FDA communicates qualified health claims and FDAMA claims on its webpages rather than through the Code of Federal Regulations.

45 21 CFR 101.14(a)(1)
46 H.R. 3562 – 101st Congress: Nutrition Labeling and Education Act of 1990
47 Food and Drug Administration. "The United States Food and Drug Administration Modernization Act (FDAMA) of 1997." (2013)
48 U.S. Food & Drug Administration. Qualified Health Claims: Letters of Enforcement Discretion. . https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims-letters-enforcement-discretion. Last updated March 7 /2022.

HEALTH CLAIMS *(CONTINUED)*

Basic Requirements for Any Health Claim Established by the FDA[49]

When the FDA issues a regulation for a health claim, the health claim is available to all companies, provided that:

- The food contains, without fortification, 10% or more of the DRV or RDI per RACC for one or more of the six nutrients shown in Table 6. Without one of these specified nutrients inherently in the food at a "good" level, a health claim is not permitted even if all other criteria are met for the specific regulation.[50] It is presumed that FDA will take enforcement discretion and permit vitamin D and potassium as supporting this health claims criteria (provided vitamin D and potassium are naturally occurring or inherent to the dairy product). At this time, vitamin D and potassium are not part of the regulations.
- The food contains less than the *disqualifying* amount per RACC and per labeled serving for total fat, saturated fat, sodium and cholesterol (see section "Disclosure Statements and Disqualifying Levels"). Some individual health claims have more, or less, restrictive specific requirements for these nutrients; for example, foods bearing the sodium/hypertension health claim must be low in sodium. See Table 3 for disqualifying nutrient levels.
- All information must be in one place without intervening material.
- The claim must frame the impact that intake, or reduced intake, might have on a disease or health-related condition in the context of a total dietary pattern.
- 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 cannot be about the diagnosis, cure, mitigation or treatment of disease.
- The claim does not quantify any degree of risk reduction.
- The claim indicates that disease depends on many factors.

TABLE 6
10% RDI or DRV for adults and children >4 years

NUTRIENT	10% DAILY VALUE
Vitamin A	90 mcg
Vitamin C	9 mg
Iron	1.8 mg
Calcium	130 mg
Protein	5 g (provided the PDCAAS has been applied to the %DV)

49 21 CFR 101.14(e)
50 21 CFR 101.14(e)(6)

HEALTH CLAIMS *(CONTINUED)*

TABLE 7.1
FDA-approved health claims that are appropriate for use on select dairy products

DIETARY COMPONENT	FDA DEFINITION, CRITERIA AND MODEL HEALTH CLAIM[a]
Osteoporosis	
Calcium and vitamin D[51]	• At least an *excellent source* of calcium (≥20% DRV per RACC) • The claim may also include vitamin D if the food is at least an *excellent source* of vitamin D (≥20% DRV per RACC) • Phosphorus content equal to or less than the calcium content • Per RACC, per labeled serving, and (if a small RACC), per 50 g,[b] the product does not exceed disqualifying levels for: Total Fat, Saturated fat, Cholesterol, Sodium • 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 260 mg calcium (20% DV) per RACC, but do not contain adequate vitamin D for the claim. Vitamin D content from fortification is not permitted to contribute to the health claim. **Model Health Claim:** *Adequate calcium [and vitamin D] throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis*
Hypertension	
Sodium[52]	• The food meets all the nutrient content requirements for *low sodium* • Per RACC, per labeled serving, and (if a small RACC) per 50 g,[b] the product does not exceed disqualifying levels for: Total Fat, Saturated fat, Cholesterol • Claim may include optional information for target populations, mechanisms for how sodium intake affect blood pressure and that medical advice can assist individuals with appropriate treatment. • 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. **Model Health Claim:** *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 part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.*

51 21 CFR 101.72b
52 21 CFR 101.74

TABLE 7.2
FDA-approved health claims that are appropriate for use on select dairy products

DIETARY COMPONENT	FDA DEFINITION, CRITERIA, AND MODEL HEALTH CLAIM[a]
Cancer	
Dietary fat[53]	• The food meets all the nutrient content requirements for *low fat* • Per RACC, per labeled serving, and (if a small RACC), per 50 g,[b] the product does not exceed disqualifying levels for: Saturated fat, Cholesterol, Sodium • Claims may provide optional information about the Dietary Guidelines for Americans, the number of USA citizens with cancer, and that cancer has other risk factors affected by one's genes and the environment. • 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. **Model Health Claim:** *Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.* OR *Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking, and what you eat.*
Coronary Heart Disease	
Saturated fat and cholesterol[54]	• The food meets all the nutrient content requirements for each of the following: *low saturated fat, low cholesterol, low fat* • Per RACC, per labeled serving, and (if a small RACC) per 50 g,[b] the product does not exceed disqualifying levels for sodium • The Nutrition Facts displays the polyunsaturated and monounsaturated fats • Claims may interchange "heart disease" with "coronary heart disease" as well as a mention may be made about some of the risk factors or dietary planning advice available from the Dietary Guidelines for Americans report. • 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 within the claim language. • 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. • Claim may include optional information for target populations — mechanisms for how elevated blood cholesterol affects the heart and that medical advice can assist individuals with appropriate treatment if the claim defines high or normal blood cholesterol. **Model Health Claim:** *Development of heart disease depends upon many factors, diets low in saturated fat and cholesterol may reduce the risk of this disease*
Hypertension and Stroke	
Potassium[55]	• The food is at least a *good source* of potassium (≥10% DRV per RACC) • The food meets all the nutrient content requirements for each of the following: *Low sodium, Low saturated fat, Low cholesterol, Low fat* • As a FDAMA authoritative statement-based claim, the exact wording provided in the notification 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.* **Model Health Claim:** *Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke (NOTE: this is a FDAMA claim so the exact language must be used)*

a. The FDA provides model claim statements for each of its health claims authorized by regulation. Manufacturers are not required to use the exact language of the model claims in the FDA regulation, but the claim must address all the information provided in the model claim. See the section *Message Criteria for Individual Health Claims* below for more details. Health claims authorized by FDAMA claim notifications and qualified health claims must use the exact claim language specified in the FDAMA claim notification or qualified health claim approval letter.

b. per 50 g if the food's RACC is 30 g or less, or 2 tbsp or less

53 21 CFR 101.73
54 21 CFR 101.75
55 FDA Modernization Act (FDAMA) Claims. "Health Claim Notification for Potassium Containing Foods" (2000).

HEALTH CLAIMS *(CONTINUED)*

TABLE 8
Potential health claims for select dairy products

	UNFLAVORED MILK (240 ML)			UNFLAVORED YOGURT (170 G)		UNFLAVORED COTTAGE CHEESE (110 G)	
HEALTH CLAIM[a]	Reduced-fat (2% milk fat)	Low-fat (1% milk fat)	Fat-free (skim)	Plain (low-fat)	Plain (fat-free)	2% milk fat	1% milk fat
Calcium, vitamin D and osteoporosis[56]	Yes (calcium only)	Yes (calcium only)	Yes (calcium only)	Yes (calcium only)	Yes (calcium only)	No	No
Sodium and hypertension[57]	Yes	Yes	Yes	Yes	Yes	No	No
Dietary fat and cancer[58]	No	Yes	Yes	Yes	Yes	Yes	Yes
Dietary saturated fat and cholesterol, and risk of coronary heart disease[59]	No	No	Yes	No	Yes	No	Yes

a. Eligibility based on nutrient values in USDA National Nutrient Database for Standard Reference, Release 28, 2016. Nutrient Data Laboratory Home Page: https://ndb.nal.usda.gov/ 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.

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 (SSA) required for the FDA to issue an Authorized Health Claim. This is why the qualified health claims are not part of the Code of Federal Regulations (CFR).

Qualifying language (e.g., *Little scientific evidence suggests that* **or** *Some evidence suggests that* **or** *Scientific evidence suggests but does not prove* **or** *For healthy infants who are not exclusively breastfed and who have a family history of allergy*) is included as part of the claim statement to explain how the evidence supporting the claim is incomplete. 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.[60]

The list of qualified health claims permitted by FDA is subject to change at any time.

56 21 CFR 101.72 and Table 7.1
57 21 CFR 101.74 and Table 7.1
58 21 CFR 101.73 and Table 7.2
59 21 CFR 101.75 and Table 7.2
60 FDA. Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. 2003. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053832.htm

STRUCTURE/FUNCTION CLAIMS

Structure/function claims[61] are label statements that describe an effect of a nutrient on the structure or functions of the human body (e.g., *calcium builds strong bones*) or a substance affecting general well-being and may be used on food labels and dietary supplement labels. The structure/function claim category does not include claims about effects related to a disease, markers of disease risk or other dysfunction-related conditions (this would be called a **disease or drug claim**).[62] For conventional food labels and labeling, structure/function claims are limited to those nutrients FDA has recognized as essential by regulation. These are the nutrients listed in the table of Daily Values. It is advisable that a structure/function claim only specify nutrients that are at least a good source (10% or more of the Daily Value) and have adequate scientific support in the public domain.

Structure/function claims are not subject to any FDA review or approval prior to use on a food label but must be truthful and not misleading. Unlike conventional foods, when structure/function claims are used on dietary supplement labels, they must be accompanied by the following boxed statement: *This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.* Dietary supplement manufacturers must also notify FDA of the structure/function claims they make once they are in commerce. Neither the boxed disclaimer statement on the label or labeling nor the FDA notification requirement apply to conventional food labels if they declare structure/function claims.

FDA refers to label statements that describe effects related to a disease or other bodily dysfunction and damage—related condition as *disease claims*. The use of disease names (other than within pre-authorized health claims) on a food label can result in the product being subject to drug regulations. Differentiating structure/function claims from disease claims is not always clear-cut. A label statement can be a disease statement based on either the explicit or implied meanings of the claim. For example, a statement that refers to characteristic signs or symptoms of a disease may infer that the intended use of the product is to treat or prevent that disease. In addition to the actual wording of a claim, the context of a claim when viewed with all information on the label will determine if the statement is a disease claim.

FDA provides industry guidelines to help manufacturers understand FDA's thinking on how to distinguish between structure/function claims and disease claims. Although the FDA guideline focuses on dietary supplement claims, the guideline also applies to structure/function claims made for conventional foods.

TABLE 9

Example wording of structure/function claims, disease claims, and authorized health claims

STRUCTURE/FUNCTION CLAIM	DISEASE CLAIM NOT PERMITTED ON CONVENTIONAL FOODS	AUTHORIZED HEALTH CLAIM[b] ESTABLISHED BY REGULATION
Calcium helps build strong bones	Calcium may prevent osteoporosis	Adequate calcium throughout life, as part of a well-balanced diet, many reduce the risk of osteoporosis.
Potassium helps maintain normal blood pressure	Potassium can reduce blood pressure Potassium helps prevent hypertension	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.
Vitamin A helps maintain normal vision	Vitamin A helps prevent macular degeneration	none

a. See Structure/Function claim section above
b. See Health Claim section above

61 21 CFR 101.93(f)
62 21 CFR 101.93(g)

STRUCTURE/FUNCTION CLAIMS *(CONTINUED)*

Substantiation

Structure/function claims must be substantiated as truthful and not misleading. FDA provides guidance that explains the FDA *credible and reliable* standard for scientific substantiation of structure/function claims. Although this guideline was prepared for the dietary supplement industry, the advice is equally relevant to the substantiation of structure/function claims for conventional foods. Claims made for effects of a food should be substantiated with evidence that the food is effective in providing the claimed effect in humans.

There is no standard formula for how to substantiate structure/function claims. How many studies and what types of evidence are needed will depend on the nature of the claim and the accepted norms in the relevant research disciplines. For example, claims about the known functions of essential nutrients, when used on the label of foods that are a good source of those nutrients, would likely not require any substantiating evidence beyond what can be found in graduate-level nutrition textbooks.

Marketers who make claims about health and nutrient-related benefits should consider how these may be interpreted by the reasonable consumer and should make sure that their claims are backed up by sound scientific evidence. The FTC's concerns about deceptive advertising have led to actions in recent years against manufacturers for immunity, weight loss and other health-related claims.

The key issues a manufacturer must consider in assessing whether the evidence to substantiate a claim meets the competent and reliable scientific evidence standard include:

(1) the meaning of the claim being made
When the claim is worded such that there is more than one reasonable interpretation, is there substantiation for each interpretation?

(2) the relationship of the evidence to the claim
Is the substantiating evidence from the same formulation, serving size and conditions of use as the labeled food? Has the substantiating evidence clearly identified and measured study endpoints relative to the claim? Was the substance tested in a population similar to that which will be using the food? Does the claim accurately reflect the extent, nature or permanence of the effect achieved in the studies?

(3) the quality of the evidence
Competent and reliable scientific evidence consists of information derived primarily from human studies conducted with appropriate randomization and blinding to minimize bias. Publication of a study in a peer-reviewed journal gives a level of assurance that qualified experts have reviewed the research and found it to be of sufficient quality and validity to merit publication.

Human research must be conducted in compliance with the U.S. requirements for institutional review found in 21 CFR 56. This includes the requirement that the study protocol be approved by an Institutional Review Board (IRB) and that the IRB monitor the study to ensure the safety of human subjects. Studies must also be registered with www.clinicaltrials.gov to further demonstrate transparency in study conduct.

(4) the totality of the evidence
Determining if a claim is substantiated requires considering all relevant evidence, both favorable and unfavorable. This means that the substantiation of a claim takes into account more than simply the results from a single study but also those studies that show no effect or refute a hypothesis.

STRUCTURE/FUNCTION CLAIMS *(CONTINUED)*

Potential structure/function claims for milk and milk products

Milk and other dairy products contain many essential nutrients that support various known, scientifically substantiated, physiological functions. Some of the known nutrient/physiological function relationships that are potential structure/function claim topics for dairy products are:

Calcium

- Calcium helps build and maintain strong bones and teeth.
- Calcium plays a key role in bone health.

Vitamin D

- Vitamin D supports calcium absorption for maintenance of healthy bones and teeth.
- Vitamin D plays a key role in bone health.

Phosphorus

- Phosphorus helps maintain healthy bones and teeth.
- Phosphorus supports tissue growth.

Vitamin A

- Vitamin A helps keep eyes healthy.
- Vitamin A helps keep skin healthy.
- Vitamin A maintains normal vision.

Riboflavin

- Riboflavin is used in energy metabolism in the body.
- B-vitamins, like riboflavin, help your body release energy from food.

Vitamin B12

- B-vitamins help your body release energy from food.
- Vitamin B12 is necessary for normal blood function.
- Vitamin B12 helps keep the nervous system healthy.

Potassium

- Potassium and maintenance of normal blood circulation

Protein

- Protein and maintenance of muscle tissue

While regulations do not prohibit the use of structure/function claims on foods that exceed the nutrient disclosure levels 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, per labeled serving, and per 50 g if the reference amount is 30 g or less (or 2 Tablespoons or less). The disclosure statement "See Nutrition Facts Panel for [nutrient] information" must be in close proximity to the structure/function claim.

OTHER CLAIMS

Several claims or terms used on food labels and in labeling that are not nutrition related claims also have been addressed by the FDA and/or other federal agencies including the FTC and USDA. These include terms, such as those described below, that refer to the production and/or processing of the product.

Fresh

The term *fresh* means "...that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation..."[63] FDA specifically mentions that pasteurized milk **can** be described as *fresh* because the term does not imply that the food is unprocessed, as consumers commonly understand that fluid milk is nearly always pasteurized. However, the term *fresh* cannot be used in labeling to describe juice that has been pasteurized or that contains pasteurized juice. The restrictions on the use of the term fresh also apply to brand names and sensory modifiers (e.g., fresh taste).

There are a few ingredient or food treatments that do not preclude the product from using the term *fresh* including:

- addition of approved waxes or coatings;
- post-harvest use of approved pesticides;
- application of a mild chloride wash or mild acid wash on produce;
- treatment of raw foods with ionizing radiation not to exceed the maximum dose of one kiloGray in accordance with 21 CFR 179.26; or
- refrigeration (as long as all other requirements[64] are met)

The terms *fresh frozen* and *frozen fresh* "mean that the food was *quickly frozen* while still fresh (i.e., the food had been recently harvested when frozen)". *Quickly frozen* means that the product was frozen by a freezing system such as a blast freezing system that ensures the food is frozen quickly and that no deterioration has taken place.[65] Blanching of the food before freezing does not preclude the product from bearing the term *fresh frozen* or *frozen fresh*.

Any yogurt (full-fat, low-fat, or nonfat) that is ultra-pasteurized prior to culturing, heat-treated after culturing or made using preservative ingredients cannot be labeled *fresh*. Therefore, any yogurt (full-fat, low-fat, or nonfat) that is ultra-pasteurized prior to culturing, heat-treated after culturing or made using preservative ingredients cannot be labeled *fresh*. Low-fat and nonfat yogurt that is pasteurized prior to culturing, not heat-treated after culturing, does not contain preservatives and otherwise complies with the provisions of 21 CFR 101.95 may be labeled as *fresh*. In addition, FDA states that pasteurized milk that is ultra-pasteurized (UP) or aseptically processed and packaged (ultra-high-temperature (UHT) cannot be labeled *fresh*.

63 21 CFR 101.95
64 21 CFR 101.95(a)
65 21 CFR 101.95(b)

OTHER CLAIMS *(CONTINUED)*

Genetically Engineered Ingredient Disclosure & Labeling

Bioengineered foods are defined by the 2016 National Bioengineered Food Disclosure Law[66]as food (a) that contains genetic material that has been modified through in vitro recombinant DNA techniques; and (b) for which the modification could not otherwise be obtained through conventional breeding or found in nature.[67]

The USDA Agriculture Marketing Service (AMS) developed the List of Bioengineered Foods to identify the crops or foods that are available in a bioengineered form throughout the world for which regulated entities must maintain records. These records will inform regulated entities about whether they must make a bioengineered food disclosure. As of January 1, 2022, all food manufactures, importers and certain retailers are required to ensure bioengineered foods are appropriately disclosed.[68,69] Given the USDA's Natural Organic Program prohibits the use of genetic engineering, certified organic foods do not contain GMOs and are therefore not subject to this law.

Foods derived from animals that consume feed containing bioengineered substances are not considered bioengineered because of the feed.[70] Dairy products including milk and cheeses from animals that have consumed GMO feed are not subject to labeling requirements because of the feed. Any product that meets USDA-organic certification requirements and recordkeeping requirements[71] can substantiate a food labeling claim indicating the product *was not produced using bioengineering.*

Grass Fed

A regulatory definition of the term grass fed has not been established by FDA. As such, claims regarding the practice of grass feeding cattle would be required to meet the standard of being truthful and not misleading. Until January 2016, the USDA AMS maintained standards for several livestock and meat marketing claims, including grass fed, designed to facilitate communications between producer and consumer to better inform purchasing decisions. The standards included a 100 percent grass or forage-based diet standard for use of the grass fed claim, although the standard did not limit the grass fed designation to animals exclusively fed live grass because of the wide range of climates across the United States. While this program was discontinued in 2016, the guidelines previously established by USDA AMS[72] could serve as a guideline for production requirements in order to establish a claim as truthful and not misleading to the consumer. In addition, several independent certification programs are available (e.g., American Grassfed Association, Certified Grassfed By A Greener World, 100% Grass-Fed Certification Program).

66 Public Law No: 114-216: A bill to reauthorize and amend the National Sea Grant College Program Act, and for other purposes. Section 1: National Bioengineered Food Disclosure Standard. July 2016. https://www.ams.usda.gov/sites/default/files/media/Final%20Bill%20S764%20GMO%20Discosure.pdf

67 7 U.S. Code § 1639 - Definitions

68 National Academies of Sciences, Engineering, and Medicine. 2016 Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: 10.17226/23395; World Health Organization Frequently asked questions on genetically modified food http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified- food/en/, May 2014.

69 Federal Register. Vol. 83, No. 87. February 19, 2019. Final rule: National Bioengineered Food Disclosure Standard. https://www.gpo.gov/fdsys/pkg/FR-2018-05-04/pdf/2018-09389. pdf.

70 FDA. Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants. March 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-labeling-indicating-whether-foods-have-or-have-not-been-derived

71 7 CFR 205.100, 7 CFR 205.103, and 205.400

72 https://www.ams.usda.gov/grades-standards/beef/grassfed, Grass Fed Marketing Claim Standard

OTHER CLAIMS *(CONTINUED)*

Lactose-free

Although the FDA has definitions for *free* nutrient content claims for some nutrients (e.g. fat free), there is no regulatory definition for *lactose-free. For free claims that are permitted by regulation, such as fat-free or sugar-free, the regulation defines the threshold level for an insignificant amount below which a food containing less than this amount (per reference amount) qualifies for the free claim, even though there may be a measurable amount of the nutrient.*

While there is no FDA definition for the terms *lactose-free* or *lactose-reduced*, manufacturers must provide food labels that are truthful and not misleading. A *lactose-free* product should not contain any lactose and a *lactose-reduced* product should have meaningful reduction.

Local

The term *local* is not defined by federal regulations and there is no generally accepted definition for local food. Some states have regulations regarding the use of this and related claims, though the requirements vary by state. For example, there is not a standard, acceptable distance between production and sale. Beyond the state requirements, any use of the term on a packaged food product or in the marketing/advertising of a food product would need to be truthful and not misleading for the consumer. It's important to consider all components of the food, including the geographical source of all ingredients (e.g., preservatives, vitamins, minerals, sweeteners, etc.) when evaluating the use of the term in conjunction with the labeling or marketing of a food product.

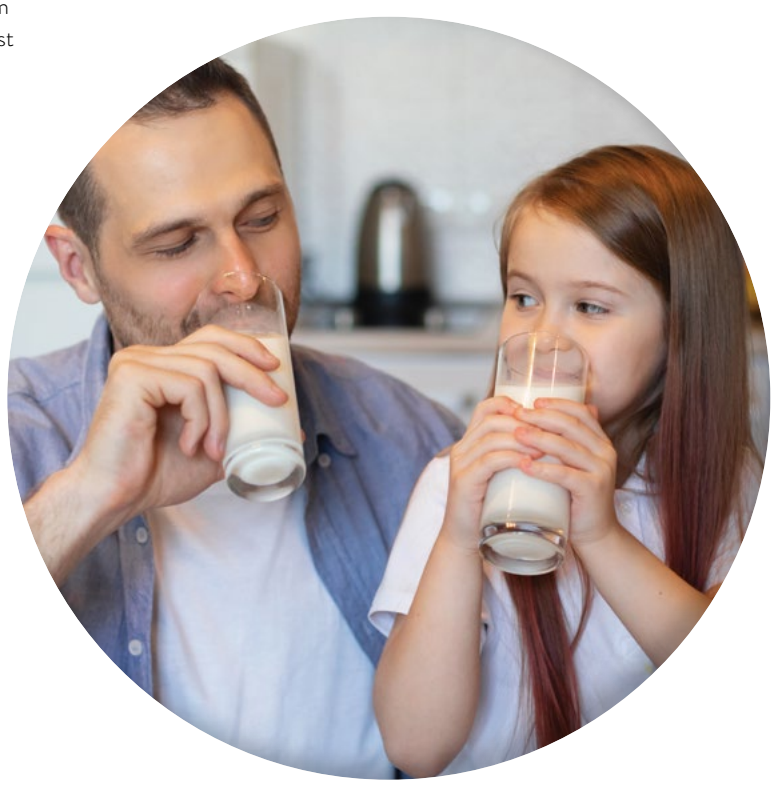
OTHER CLAIMS *(CONTINUED)*

Natural

The FDA has not defined the term *natural* in food labeling regulations; however, FDA has a long-standing policy regarding the use of the term *natural* on food labels. FDA has stated that they would not object to the use of the term except for those foods with added color (regardless of source), synthetic substances (like chemical preservatives) and artificial flavors. FDA considers *natural* to mean that nothing artificial or synthetic (including colors regardless of source) is included in or has been added to the product that would not normally be expected to be there.[73] FDA evaluates the use of the term on a case-by-case basis and all claims must be truthful and not misleading.

For meat and poultry products that are regulated by USDA, the Food Safety and Information Service (FSIS) defines a *natural* product as one containing no artificial ingredient or added color and is only minimally processed.[74] Minimal processing means that the product was processed in a manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term *natural* (such as *no artificial ingredients; minimally processed*). In contrast to FDA, FSIS maintains an approval process for all meat and poultry labels bearing such claims, which allows them to evaluate the use of the term on individual products on a case-by-case basis.

In 2016, the FDA opened a public comment period regarding the definition of *natural* in the labeling of food products.[75] FDA requested public input on the use of the term natural in conjunction with food products containing genetically engineered ingredients, processed foods and the use of synthetic vitamins among other topics. No additional updates were available as of November 2022.



73 58 Federal Register 2302 at 2407 (January 6, 1993); 56 Federal Register 60421 at 60466 (November 27, 1991)

74 USDA Food Safety And Inspection Service. Food Standards and Labeling Policy Book. August 2005 https://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5- b95a128f04ae/Labeling-Policy-Book.pdf?MOD=AJPERES

75 FDA-2014-N-1207 https://www.regulations.gov/docket?D=FDA-2014-N-1207

OTHER CLAIMS *(CONTINUED)*

Organic

In accordance with the Organic Foods Production Act, the USDA has developed regulations regarding organic food production and labeling. The USDA Agricultural Marketing Service (AMS) oversees the National Organic Program (NOP). When a food label uses the term *organic* both production of the agricultural ingredients and the processing of the food product must meet the NOP definition of organic and be certified *organic* by a USDA-licensed certifying body.[76]

To qualify for organic labeling, dairy products must be made of milk from dairy cows raised on organic feed and by organic livestock standards as defined in the USDA National Organic Program. These standards require that animals have access to outdoor pasture and prohibit the use of growth hormones and prophylactic antibiotics but allow vaccines and treatment for sick animals from a pre- approved list of substances reviewed periodically.[77]

The National Organic Program includes four levels of organic labeling standards based on the percentage of organic ingredients in food.

76 USDA. National Organic Program. https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program
77 7 CFR 205.238 and 239

OTHER CLAIMS *(CONTINUED)*

TABLE 10
National Organic Program Labeling Claims

CLAIM CATEGORY	% ORGANIC INGREDIENTS CERTIFIED[a]	REQUIRED LABELING STATEMENTS IMMEDIATELY AFTER THE BUSINESS ADDRESS[b]	ALLOWABLE LABELING STATEMENTS[c]	USE OF USDA ORGANIC SEAL PERMITTED?[d,e]
100% Organic	100%	• Identification of the Certifying Agent • Identification of organic ingredients unless a single, organically certified, ingredient product	*100% Organic*	Yes
Organic	At least 95%[f] Remaining 5% of ingredients must not be made with prohibited methods	• Identification of the Certifying Agent • Identification of organic ingredients	*Organic* *__% Organic* *__% Organic ingredients*	Yes
Made with Organic Ingredients	At least 70% Remaining ingredients must not be made by prohibited methods	• Identification of the Certifying Agent • Identification of organic ingredients	*Made with organic ____ [berries, cream and butter]* May state "made with organic [insert up to three ingredients – OR – Ingredient categories]."	No
Contains a Specific Organic ingredient	Can contain less than 70%		• Organic ingredients may be identified only within the ingredient list • A *% Organic* claim may be made on the Information Panel only • No organic claims permitted anywhere on the label outside of the ingredient statement • No required labeling statements	No

a. Ingredients in the product, except added water and salt, must be organically produced. Products that are *not* 100% organic (e.g. 95% organic) may contain non-organic ingredients listed in the National List of Allowed and Prohibited Substances, such as dairy cultures, natural flavors, and select colors derived from agricultural products. This list is continually evolving and must be reviewed every year.[78]

b. There are requirements for the placement of organic statements and logos on the package label.[79]

c. *100% Organic* and *Organic* must be used in conjunction with the product name (statement of identity). Ingredients must be declared organic in the ingredient statement but a symbol next to each ingredient may be used to consolidate the declaration (and if the symbol is connected to the word "Organic" or "Organic ingredient" at the end of the ingredient statement). Other than these statements the label must not make any other reference to organic contents.

d. The USDA Organic seal is available for download at www.ams.usda.gov/nop/Consumers/Seal.html

e. The use of the certifying agent's seal and/or business address is a matter of the agent's business agreement with the manufacturer. It is not a requirement of the USDA National Organic Program to display the seal: it is only a requirement to declare the name of the certifying agent after "Certified Organic By ____".

f. In a certified (95%) organic product, the remaining 5% of non-organic ingredients (excluding water and salt) must meet these three initial criteria that the certified organic ingredients also meet by definition: (1) Must not contain genetically modified ingredients (GMO's), (2) Must not be irradiated (exposed to ionizing radiation), and (3) If they are agricultural, they must not have been fertilized with sewage sludge. Those agricultural products that make-up the 5% must be from certified organic sources, if available, and price may not be the deciding factor. If the remaining 5% is from non-organic sources, the agricultural and non-agricultural ingredients must be approved for use per 21 CFR 205.605 and 205.606, the National List of Allowed and prohibited Substances.[80]

78 7 CFR 205.605 and 606; http://www.ams.usda.gov/nop/NationalList/ListHome.html
79 7 CFR 205.605 and 606; http://www.ams.usda.gov/nop/NationalList/ListHome.html
80 7 CFR 205.311

OTHER CLAIMS *(CONTINUED)*

Recombinant Bovine Somatotropin (rbST)

In 1993 FDA approved the use of recombinant bovine somatotropin (rbST) or a recombinant bovine growth hormone (rbGH) for lactating dairy cows to increase the production of marketable milk. FDA determined after a thorough review that rbST is safe and effective for dairy cows, that milk from rbST treated cows is safe for human consumption and use of the product does not have a significant impact on the environment.[81]

rbST claims must be truthful, not misleading and should comply with FDA guidance regarding specific label statement be used on products bearing a rbST claim. FDA has indicated that the rbST claims be supported with qualifying language on the same panel that has the following meaning: *From cows not treated with rbST. No significant difference has been shown between milk derived from rbST-treated and non-rbST treated cows.*[82] Other label statements can also meet FDA's requirement of providing adequate context, such as an overall explanation of organic milk and how it's produced.

Statements regarding rbST cannot allow a consumer to conclude that milk from untreated cows is safer or of higher quality than other milk. Labels should not use statements such as *hormone-free* or *rbST-free.* FDA considers these false and misleading because all milk naturally contains hormones (including a very low concentration of bovine somatotropin; bST)[83,84] and no milk is therefore *bST-free.* Also, an *rbST-free* claim may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk was produced. Instead, *from cows not treated with rbST* or similar statements can be used. All claims must be substantiated with documentation on file that all statements are truthful.

81 FDA. Bovine Somatotropin (bST). (April 2022) https://www.fda.gov/animal-veterinary/product-safety-information/bovine-somatotropin-bst

82 59 Federal Register (February 10, 1994) Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin https://www.govinfo.gov/app/details/FR-1994-02-10/94-3214

83 Vicini J, Etherton T, Kris-Etherton P, et al. Survey of Retail Milk Composition as Affected by Label Claims Regarding Farm-Management Practices. J Am Diet Assoc 2008;108:1198-1203.

84 U.S Food and Drug Administration has stated, "When they are eaten, proteins are broken down by digestive enzymes in the human gastrointestinal tract. Furthermore, even if it was injected, the human body doesn't recognize bST because its structure is significantly different from the somatotropin produced in the human pituitary gland." https://www.fda.gov/animalveterinary/safetyhealth/productsafetyinformation/ucm055435.htm

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY

Nutrient Fortification: General and Dairy-Specific

Fortification means adding nutrients to conventional foods, including beverages, and is synonymous with enrichment based on FDA regulation and enforcement.[85] Food industry members traditionally consider fortification as the addition of nutrients that were not present in the original food or ingredient; while enrichment has implied the restoration of nutrients that may have been reduced due to processing or storage effects. The use of *enriched* or *fortified* is a nutrient content claim when applied to dairy product labeling.

Long-established FDA policy has been that there will be no mandatory nutrient fortification of food in the United States, nor will fortification be prohibited if there is a documented public health need.[86] There are restrictions on maximum use levels for some nutrients included in food additive regulations based on safety, and the levels of optional nutrient fortification of standardized foods (e.g., vitamins A & D in fluid milk[87]) are specified in their food standards regulations. Even where specifically defined for an enriched standardized food, fortification is voluntary and discretionary. In 1977, the FDA adopted a fortification policy to establish a uniform set of principles for the rational addition of nutrients to foods.[88] The nutritional guideline discourages random fortification of foods, noting that this could result in nutrient 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.

Nutrient Fortification of Milk and Milk Products — Vitamin A

Milk

The addition of vitamin A (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) is mandatory in lower fat milk and milk products (except yogurt) to achieve nutritional equivalency with their full-fat counterparts.[89] The ingredient statement must include the nutrient additive by its common or usual name. If vitamin A is added to milk, it must be added at a level to achieve a minimum of 2000 IU per quart thereof within the limits of good manufacturing practice.[90] The acceptable range for vitamin A is 2000-3000 IU per quart.[91] When the nutrient is added, a declaration is required adjacent to each placement of the product name (statement of identity), such as "Vitamin A added."

Cheese

Vitamin A (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) may be added to cheese within current good manufacturing practice conditions of use.[92] Lower fat cheese products such as reduced-fat and low-fat cheeses must be fortified with vitamin A to achieve nutritional equivalency with their full fat counterparts.[93] The ingredient statement must include the use of this nutrient additive by its common or usual name. When the nutrient is added, a declaration is required adjacent to each placement of the product name (statement of identity), such as "Vitamin A added."

85 21 CFR 101.54(e)
86 Institute of Medicine of the National Academies. Guiding Principles for Nutrition Labeling and Fortification. 2003
87 21 CFR 131.110
88 21 CFR 104.20
89 21 CFR 130.10(b)
90 921 CFR 131.110 (b)(1)
91 U.S. Department of Health and Human Services; Public Health Service; Food and Drug Administration. Pasteurized Milk Ordinance 2019.
92 21 CFR 184.1930
93 21 CFR 130.10(b)

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Yogurt
The addition of vitamin A to yogurt is optional. If added, the minimum amount of vitamin A in each 946 milliliters (1 quart) of the food must not be less than 2000 IU, within the limits of current good manufacturing practice.[94] Unlike low-fat milk and fat-free milk, low-fat yogurt and fat-free yogurt are not required to be fortified with vitamin A. The ingredient statement must include the use of this nutrient additive by its common or usual name. When the nutrient is added, a declaration is required adjacent to each placement of the product name (statement of identity), such as "Vitamin A added." As of June 2021, the FDA has issued a final rule to amend and modernize the standard identity for yogurt by allowing for greater flexibility in yogurt production. Under this rule, low-fat yogurt and fat-free yogurt would no longer have separate standards of identity and will be covered under the FDA's general definition and standard of identity for yogurt. Changes allow manufacturers to fortify yogurt with vitamins A and D so long as they meet fortification requirements.[95]

Nutrient Fortification of Milk and Milk Products- Vitamin D
The addition of vitamin D (vitamin D2 or D3 in crystalline, resin or crystal form) to all milk and milk products is optional and may be added within the limits of good manufacturing practice.[96] Many standards of identity prescribe the minimum level of vitamin D that must be present if it is to be added to a product. 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 current regulations.[97] The ingredient statement must include the use of this nutrient additive by its common or usual name. For dairy products this has historically been "Vitamin D3" or "Vitamin D2." At this time, other forms or sources of the vitamin additive (e.g., mushroom powder) are not permitted in dairy products by FDA. When the nutrient is added, a declaration is required adjacent to the product name, such as "Vitamin D added."

Milk
If vitamin D is added to milk, the amount added must achieve a minimum of 400 IU of vitamin D per quart within the limits of good manufacturing practice.[98] The acceptable range for vitamin D is 400-600 IU per quart of milk.[99] The ingredient statement must include the use of this nutrient additive by its common or usual name. For dairy products this has historically been "Vitamin D3"or "Vitamin D2." At this time, other forms or sources of the vitamin additive (e.g., mushroom powder) are not permitted in dairy products by FDA. When the nutrient is added, a declaration is required adjacent to the product name, such as "Vitamin D added."

Cheese
Vitamin D (vitamin D2 or D3 in crystalline or resin form) may be added to cheese, at a level of 89 IU/100 grams.[100] In 2005, the FDA authorized the use of vitamin D3 at levels up to 81 IU/30 g in cheese and cheese products that have a reference amount of 30 grams,[101] which is 10% of the Daily Value. Excluded from this rule are cottage cheese, ricotta cheese, and hard grating cheeses, such as Parmesan and Romano and those cheeses defined by 21 CFR 133.148. The ingredient statement must include the use of this nutrient additive by its common or usual name. For dairy products, this has historically been "Vitamin D3" or "Vitamin D2."

At this time, other forms or sources of the vitamin additive (e.g., mushroom powder) are not permitted in dairy products by FDA. When the nutrient is added, a declaration is required adjacent to the product name, such as "Vitamin D added."

Yogurt
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.[102] The ingredient statement must include the use of this nutrient additive by its common or usual name. For dairy products this has historically been "Vitamin D3" or "Vitamin D2." At this time, other forms or sources of the vitamin additive (e.g., mushroom powder) are not permitted in dairy products by FDA. When the nutrient is added, a declaration is required adjacent to the product name, such as "Vitamin D added."

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.[103]

94 21 CFR 131.200, 131.203, 131.206
95 86 FR 31117. Milk and Cream Products and Yogurt Products; Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt (2021).
96 21 CFR 184.1950
97 21 CFR 184.1950 or 172.379 and 172.380
98 21 CFR 131.110 (b)(2)
99 U.S. Department of Health and Human Services; Public Health Service; Food and Drug Administration. Pasteurized Milk Ordinance 2019.
100 21 CFR 184.1950
101 21 CFR 172.380
102 21 CFR 131.200, 131.203, 131.206
103 21 CFR 104.20

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Federal Standards of Identity for Dairy Foods

U.S. food standards are designed to promote fair competition among food manufacturers and avoid consumer confusion. These standards may or may not match the regulations of other countries or even the international Codex Alimentarius. The federal standards of identity include definitions; process of producing the product; required and optional ingredients; product nomenclature; required and voluntary label declarations; and methods of analysis.[104]

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 use of nutrient content descriptors, other requirements of the standard must be met, unless otherwise exempted.

Many dairy products are subject to a standard of identity established by FDA regulations.[105] A standard of identity can define a specific product (e.g., Cheddar cheese or milk)[106]or it can encompass an entire category of food (e.g., grated cheeses).[107]

TABLE 11

Regulations and specific requirements for standardized dairy products

CLASS OF DAIRY PRODUCTS	SECTION IN CFR
Milk and Cream Includes milk; acidified milk; cultured milk; concentrated milk; sweetened condensed milk; nonfat dry milk; nonfat dry milk fortified with vitamins A and D; evaporated milk; dry whole milk; dry cream; heavy cream; light cream; light whipping cream; sour cream; acidified sour cream; eggnog; half-and-half; 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 and 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
- Does not contain ingredient(s) required by the standard
- Contains an amount of an ingredient or component not within the limitations of the 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,[108] marketing a product with a standard of identity and a nutrient content claim,[109] and marketing a product in a state or area that has been granted an exemption.

104 21 CFR 130; 130.3; 130.5
105 21 CFRs 131; 133; 135
106 21 CFR 133.113 and 133.110
107 21 CFR 133.146
108 21 CFR 130.17
109 21 CFR 130.10

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Grade "A" Pasteurized Milk Ordinance

The Grade "A" Pasteurized Milk Ordinance (PMO)[110] provides additional guidelines for labeling 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.

All bottles, containers and packages enclosing Grade A milk and milk products must be labeled in accordance with the requirements of the Federal Food, Drug and Cosmetic Act, and all applicable regulations in the Code of Federal Regulations. In addition, the products must be conspicuously marked with:

- 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 (e.g., Goat Milk)
- The words "Grade A" on the exterior surface, meaning principal display panel at a minimum, with additional (voluntary) disclosures on the secondary information panel or the cap/cover.
- The word "reconstituted" or "recombined" if applicable to the product.
- Additional information if the product is condensed or dry milk must appear on the principal display panel.
- In some states, a date code is required for products with a shelf-life of less than 30 days.
- "Keep refrigerated" or "Keep frozen" are required on the principal display panel for potentially hazardous foods like fluid dairy products that require controlled storage conditions to keep food safe.

Processing and Sweetener Definitions

The following terms, described here as processing and nutrient or ingredient definitions, are select examples of definitions from the Code of Federal Regulations[111] and/or the latest revision of the Pasteurized Milk Ordinance (PMO)[112] that are relevant to standards of identity.

Pasteurized

When used to describe milk and milk products, pasteurization means that the product has been heated by properly operated equipment to one of the temperatures specified in its regulation.[113] The PMO 2019 offers additional time/temperature relationships for the terms pasteurization, pasteurized and similar terms. There are four FDA recognized methods for milk pasteurization: High Temperature Short Time, Higher Heat Shorter Time, Ultra High Temperature and Ultra Pasteurized. Milk that is in final package form for beverage use must be pasteurized or ultra-pasteurized.[114] The label may optionally indicate the milk is "pasteurized."[115]

Ultra-pasteurized

Ultra-pasteurized milk and milk products have been thermally processed at or above 280°F (138°C) for at least two seconds, either before or after packaging, to produce a product that has an extended shelf life under refrigerated conditions.[116] If milk has been ultra-pasteurized, the label must indicate "ultra-pasteurized."[117]

Aseptic processing and packaging

Aseptic processing and packaging is the filling of a commercially sterilized, cooled product into pre-sterilized containers, followed by aseptic hermetical sealing, with a pre-sterilized closure, in an atmosphere free of microorganisms. The product must maintain commercial sterility under ambient conditions.[118]

110 U.S. Department of Health and Human Services; Public Health Service; Food and Drug Administration. Pasteurized Milk Ordinance 2019.
111 21 CFR 130, 131, 133
112 U.S. Department of Health and Human Services; Public Health Service; Food and Drug Administration. Pasteurized Milk Ordinance 2019
113 21 CFR 131.3
114 21 CFR 131.110(a)
115 21 CFR 131.110(e)(2)(i)
116 21 CFR 131.3(c)
117 21 CFR 131.110(e)(1)(ii)
118 U.S. Department of Health and Human Services; Public Health Service; Food and Drug Administration. Pasteurized Milk Ordinance 2019; 21 CFR 108, 110, 113

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Homogenized
In homogenized milk, the fat globule size of the milk or milk product has been reduced to such an extent that after 48 hours of storage, no visible cream separation occurs. Whole milk is forced through small openings at extremely high pressures to accomplish this process.[119] Homogenization of milk is optional. The label of homogenized milk may indicate *homogenized*.[120]

Reconstituted or recombined milk and/or milk products
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. In some cases, state law will not permit the sale of reconstituted or recombined milk and/or milk products.[121] The term does not refer to blending milk from one animal species with another (such as cow's milk and water buffalo milk to make cheese).

Nutritive sweeteners and nutritive carbohydrate sweeteners
Distinguished within the Federal Standards of Identity are the acceptable uses of ingredients to provide a sweet sensory experience. Nutritive sweeteners are substances with more than 2% of the caloric value of sucrose per equivalent unit of sweetening capacity.[122,123] 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 may be used.

For products promoted in weight loss dietary patterns, callouts must be made on the principal display panel when non-nutritive ingredients are used to achieve the properties.[124]

TABLE 12
Milk and milk product standards of identity which provide for nutritive sweeteners and nutritive carbohydrate sweeteners

STANDARDS PERMITTING USE OF NUTRITIVE SWEETENERS	STANDARDS PERMITTING USE OF NUTRITIVE CARBOHYDRATE SWEETENERS († requires disclosure the product is sweetened wherever the product name appears in specific products unless a flavoring is added)
• Milk [21 CFR 131.110(c)(2)] • Heavy cream [21 CFR 131.50(b)(3)] • Light cream [21 CFR 131.155(b)(3)] • Light whipping cream [21 CFR 131.157(b)(3)] • Sour cream [21 CFR 131.160(b)(4)] • Acidified sour cream [21 CFR 131.162(b)(3)] • Half-and-half [21 CFR 131.180(b)(3)]	• Nonfat dry milk with and without fortification of vitamins A & D [21 CFR 131.125(b)] • Evaporated milk [21 CFR 131.130(c)(4)] • Dry whole milk (21 CFR 131.147(c)(6)] • Dry cream† [21 CFR 131.149(b)(5)] • Cultured milk† [21 CFR 131.112(d)(2)] • Yogurt† [21 CFR 131.200(d)(2)] • Low-fat yogurt† [21 CFR 131.203(d)(2)] • Non-fat yogurt† [21 CFR 131.206(d)(2)] • Eggnog (required to contain a nutritive carbohydrate sweetener) [21 CFR 131.170(d)]

119 Dairy processing handbook. Second, revised edition. Tetra Pak Processing Systems AB. 2015.
120 21 CFR 131.110
121 U.S. Department of Health and Human Services; Public Health Service; Food and Drug Administration. Pasteurized Milk Ordinance 2019
122 21 CFR 170.3
123 U.S. Food & Drug Administration. Additional Information about High-Intensity Sweeteners Permitted for Use in Food in the United States. https://www.fda.gov/food/food-additives-petitions/additional-information-about-high-intensity-sweeteners-permitted-use-food-united-states. Accessed 27-Sep-22 FDA States, "Nutritive sweeteners add caloric value to the foods that contain them, while non-nutritive sweeteners are very low in calories or contain no calories at all. Specifically, aspartame, the only approved nutritive high-intensity sweetener, contains more than two percent of the calories in an equivalent amount of sugar, as opposed to non-nutritive sweeteners that contain less than two percent of the calories in an equivalent amount of sugar."
124 21 CFR 105.66

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Non-nutritive sweeteners

Eight non-nutritive sweeteners have been approved by the FDA: aspartame, acesulfame potassium, luo han guo (monk) fruit extract, neotame, saccharin, stevia, sucralose and advantame. These provide less than 2% of the caloric value of the sucrose per-equivalent sweetening capacity.[125] Non-nutritive sweeteners are zero or low calorie alternatives to nutritive sweeteners that are not completely absorbed by the digestive system and therefore provide fewer calories per gram than sugar.

In accordance with 21 CFR Part 170 and 172, food additives, such as non-nutritive sweeteners, are permitted to be used under good manufacturing practices at levels for their intended use to provide a sweet sensory taste profile to finished products

If the use of non-nutritive sweetners is for nutrient content claim purposes (e.g., *reduced sugar*, *no sugar added*), then exception to standard of identity is permitted,[126] In this case, the sweetener must be followed in the ingredient statement by an asterisk referring to a footnote that reads "Ingredient not in regular [food]".[127] 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 ingredient

In regards to milk and milk product regulations, an ingredient that performs an appropriate technical function in the food is used at a level no higher than necessary to achieve the intended purpose in that food and is not a food additive or color additive that is prohibited in conventional foods or by a standard of identity.[128] Specifically, some standards of identity for dairy products indicate "Characterizing flavoring ingredients, with or without coloring" or "Color additives that do not impart a color simulating that of milkfat or butterfat" or "color additives" for yogurt only.

Determining a Product Name

The label of a packaged food sold at retail including over the internet must include an appropriate product name, also called a "statement of identity".[129] 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 (as found in the Code of Federal Regulations)?
- Is there a common or usual name (readily understood within the U.S.)?
- 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 Federal Standard of Identity for Dairy Products section above]. The standard of identity for individual foods provides a definition of that food and specifies the appropriate product name. For example, *Cheddar cheese*.[130] 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.[131]

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).[132]

125 21 CFR 170.3
126 21 CFR 130.10
127 21 CFR 130.10(2)
128 21 CFR 130.3(d)
129 21 CFR 101.3
130 21 CFR 133.113
131 21 CFR 131.110
132 21 CFR 133.146

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Common or Usual Product Name

A common or usual name is one that is most commonly used by manufacturers and well understood by consumers.[133] 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 as derived from focus group research, 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 including slang.

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. This may be the case as more foreign products and culinary trends are introduced into U.S. commerce.

Descriptive Terms and/or Fanciful Names

If both a standard of identity and an identifiable common or usual product name are not available, a descriptive term may be used. The descriptive term 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 and more often when the product can be viewed through transparent packaging).[134]

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.*

In selecting a fanciful name, ensure the terms are not registered trademarks by seeking legal advice.

133 21 CFR 101.3(b) and 102.5
134 21 CFR 101.3(b)(3)

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Other Considerations for Product Naming

Standardized Name with a Nutrient Content Claim

If there is a name established by regulation (e.g. a standardized food with a standard of identity) that is the name that must be used as the common or usual name. Either a standardized name (e.g., *Cheddar cheese* or *Milk*) or a standardized name with a nutrient content claim (e.g., *reduced-fat Cheddar cheese* or *low-fat Milk*) are acceptable. When a product is named using a standardized name with a nutrient content claim, there is flexibility in ingredients granted to the product as long as any ingredient not normally allowed in the standardized product is added to the modified product to make the modified product comparable to the original food.[135] An example would be the use of thickeners (gums) in reduced fat milk to provide a mouth feel and appearance similar to whole milk.

This FDA regulation essentially creates a "generic standard" that allows products with a standard of identity to bear an approved nutrient content claim.[136] 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. Standardized foods modified to make a nutrient content claim may also add "safe and suitable" ingredients, which are not provided in the standard, to "improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food". However, in the event such ingredients are not permitted under the standard (or not permitted in excess of a certain level), the ingredient(s) must be specifically identified by an asterisk and one of the following statements must follow the entire ingredient statement: **Ingredient(s) not in regular _____ or *Ingredient(s) in excess of amount permitted in regular _____* (the blanks are filled in with the name of the traditional standardized food). If appropriate, both statements must be presented. The qualifying statements must appear in the same type size as the ingredient statement.

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[137] 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.

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. A product is considered nutritionally inferior if it contains a reduction of 2% or more of the DRV of protein and 2% or more of the RDI of any essential vitamin or mineral excluding nutrients of public health concern such as total fat, calories or sodium.[138]

Combination Foods or "Multifood"

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

135 21 CFR 130.10
136 21 CFR 130.10
137 21 CFR 101.3(c)
138 21 CFR 101.3(e); Federal Register May 27, 2016 Vol. 81 No. 103 *Food and Drug Administration Food Labeling: Revision of the Nutrition and Supplement Facts Labels* Final Rules

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

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.[139] 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.[140] 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 according to regulations, too.

Determining an Ingredient Name

The Federal Food, Drug, and Cosmetic Act requires that, for a food that is made from two or more in ingredients, each ingredient must be declared on the food label by its common or usual name.[141] There are many locations within FDA regulations where common or usual names of specific ingredients have been specified by regulation, including: [21 CFR 101.4] Food; designation of ingredients, the food standards of identity [21 CFR, Parts 130-169], the food additive regulations [21 CFR, Parts 170-189] and the color additive regulations [21 CFR, Parts 70-82]. In those instances where an ingredient is designated by reference under two different names, FDA generally considers the name designated under the standard of identity to take precedence.

The common or usual name of an ingredient must accurately identify or describe in as simple and direct terms as possible, the basic nature of the food (ingredient) or its characterizing properties, and the name must be uniform among all identical or similar products.[142] The specific name of an ingredient must be used in the ingredient statement, not a generic name. For example, *sweeteners* is a generic name for the more specific ingredient names such as *high fructose corn syrup, steviol glycosides, sugar* and *maple syrup*. There are a few situations where FDA regulations permits the use of a generic name for typical ingredients used in dairy products (see Table 13).

139 21 CFR 101.22
140 21 CFR 101.22(i)(1)
141 Federal Food, Drug, and Cosmetic Act Section 403(i)(2)
142 21 CFR 102.5 *General principles*

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY *(CONTINUED)*

Some of the more frequently used ingredients in dairy products and their common or usual names are shown below.

TABLE 13
Common or usual names for typical ingredients used in dairy products

INGREDIENT	COMMON OR USUAL NAME
skim milk, concentrated skim milk, reconstituted skim milk and nonfat dry milk[a,b]	*skim milk* or *nonfat milk*
milk, concentrated milk, reconstituted milk and dry whole milk[a,b]	*milk*
bacterial cultures[a,b,c,d,e]	*Cultures,* *cultured ____* (name of the substrate) Cheese cultures
sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk and dried sweetcream buttermilk[b]	*buttermilk*
whey, concentrated whey, reconstituted whey and dried whey[b]	*whey*
cream, reconstituted cream, dried cream and plastic cream (sometimes known as concentrated milk fat)[b]	*cream*
butteroil and anhydrous butterfat[b]	*butterfat*
dried whole eggs, frozen whole eggs and liquid whole eggs[b]	*eggs*
dried egg whites, frozen egg whites and liquid egg whites[b]	*egg whites*
dried egg yolks, frozen egg yolks and liquid egg yolks[b]	*egg yolks*
milk-clotting or setting enzymes[a,e]	*enzymes*

a. 21 CFR 133.129 *Dry curd cottage cheese*
b. 21 CFR 101.4 *Food; designation of ingredients.* FDA permits the omission of "dried' and "powdered" from several dairy products; this is not the case with other food ingredients.
c. 21 CFR 131.160 *Sour cream*
d. 21 CFR 131.162 *Acidified sour cream*
e. 21 CFR 133.128 *Cottage cheese*

"New" common or usual names may replace chemical or technical words in the ingredient statement by the establishment of the name through common usage and/or the filing of a citizen petition.[143] BHA (butylated hydroxy anisole), BHT (butylated hydroxy toluene) and canola oil (low erucic acid rapeseed oil) are examples of less technical and simpler names which have been established as "new" common or usual names and may be used in place of the more technical common or usual name.

When an ingredient is used as a preservative (to extend shelf-life or prevent spoilage), the functionality must be disclosed after the ingredient. Consumer friendly terms may replace the word "preservative," such as "BHA (to protect quality)." The term "to protect freshness" is not permitted as a replacement for preservative as the regulated term "fresh" does not permit the food to contain preservatives.[144]

143 21 CFR 10.30 Citizen petition
144 21 CFR 101.22 and 101.95

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RESOURCES

Innovation Center for U.S. Dairy
https://www.usdairy.com/about-us/innovation-center

Federal Trade Commission, Bureau of Consumer Protection
https://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection

Dairy Management Inc.™
https://www.USdairy.com/

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

Code of Federal Regulations (CFR), Title 21, Parts 100-169
https://www.ecfr.gov/cgi-bin/text-idx?SID=a79704a666bc14de73a3cfed93264fd1&mc=true&tpl=/ecfrbrowse/Title21/21cfrv2_02. tpl#0

Grade "A" Pasteurized Milk Ordinance 2019
https://www.fda.gov/media/140394/download

Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition Food Labeling and Nutrition
https://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/whatwedo/

U.S. Department of Agriculture, Agricultural Research Service, USDA Food Data Central, released April 2019
https://fdc.nal.usda.gov/index.html

Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition "The Food Labeling Guide"
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm

APPENDIX

TABLE 14
Fat and saturated fat claims

CLAIM[a]	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS[b]	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Fat-free[145]	• *Free of fat* • *Fat-free* • *No fat* • *Negligible source of fat* • *Zero fat* • *Without fat* • *Skim (milk only)*	Less than 0.5 g total fat per RACC and per labeled serving size. No added fat unless the food contains any ingredient that is a fat or that would be understood by consumers to contain fat, then the name of that ingredient in the label's ingredient list must have an asterisk (*) referring to a footnote such as **Adds a trivial amount of fat.* Food must be processed to achieve fat-free composition (otherwise the product is a "fat-free food").	1, 3	• Fat-free milk • Fat-free yogurt • Fat free cheese
Low-fat[146]	• *Low in fat* • *Low source of fat* • *Little fat* • *Contains a small amount of fat*	Maximum of 3 g total fat per RACC (when RACC is greater than 30 g or 2 tbsp). Maximum of 3 g total fat per RACC. (Additionally, when RACC is 30 g or less, or ≤ 2 tbsp, it has to meet these requirements per 50 g of food). Food must be processed to achieve low-fat composition (otherwise claim is, "product, a low-fat food").	1, 3	• Low-fat (white and flavored) milk (1% milk fat) • Low-fat (plain and flavored) yogurt • Low-fat cottage cheese (1% and 2% milk fat) • Orange sherbet
Reduced-fat[147]	• *Reduced in fat* • *Fat reduced* • *Less fat* • *Lower fat* • *Lower in fat*	At least a 25% reduction in total fat per RACC in comparison to an appropriate reference food.[148] Claim cannot be made if reference (comparison) food meets definition for *low-fat*. NOTE that a *reduced claim is a relative nutrient content claim.* See statement requirements in this table footnote.	1, 2	• Reduced-fat milk (plain and flavored) 2% milk fat) • Low-fat Greek yogurt (plain and flavored) • Light ice cream • Many of the *reduced-fat* and *light* cheeses, butters and other dairy products
Percent fat-free[149]	• *___% fat-free*	May be used if the product meets the requirements for *low-fat*. The percent declared and the words *fat free* need to be the same type size	1, 3, 4	• Low-fat (white and flavored) milk (1% milk fat) • Low-fat (plain and flavored) yogurt • Low-fat cottage cheese (1% and 2% milk fat) • Orange sherbet
	• *100% fat-free*	*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.	1, 3, 4	• Fat-free milk • Fat-free yogurt

145 21 CFR 101.62 (b)(1)
146 21 CFR 101.62 (b)(2)
147 21 CFR 101.62 (b)(4)
148 21 CFR 101.13(j)
149 21 CFR 101.62 (b)(6)

APPENDIX *(CONTINUED)*

Saturated fat-free[150]	• *Free of saturated fat* • *No saturated fat* • *Trivial source of saturated fat* • *Zero saturated fat* • *Without saturated fat* • *Negligible source of saturated fat*	Less than 0.5 g saturated fat and less than 0.5 g trans fatty acids per RACC and per labeled serving size. 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 list, is accompanied by an asterisk (*) that refers consumers to the statement **Adds a trivial amount of saturated fat.* or similar specified statement.) Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Disclosure of cholesterol and (total) fat is unnecessary if the food contains less than 2 mg of cholesterol and 0.5 g fat per RACC.	1, 3, 4	• Fat-free milk • Fat-free yogurt • Fat-free cheese
Low in saturated fat[151]	• *Low saturated fat* • *Low source of saturated fat* • *A little saturated fat* • *Contains a small amount of saturated fat*	Contains 1 g or less of saturated fatty acids per RACC and derives no more than 15% of calories from saturated fatty acids. Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Disclosure of cholesterol and (total) fat is unnecessary if the food contains less than 2 mg of cholesterol and 0.5 g fat per RACC.	1, 3, 4	• Low-fat cottage cheese (1% milk fat)
Reduced in saturated fat[152]	• *Reduced saturated fat* • *Saturated fat reduced* • *Lower saturated fat* • *Lower in saturated fat* • *Less saturated fat*	At least a 25% reduction in saturated fat per RACC in comparison to an appropriate reference food.[153] Claim cannot be made if reference (comparison) food meets definition for *low-saturated fat.* Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Disclosure of cholesterol and (total) fat is unnecessary if the food contains less than 2 mg of cholesterol and 0.5 g fat per RACC.	1, 2, 4	• Reduced-fat (white and flavored) milk (2% milk fat) compared with whole milk (white and flavored, respectively) • Low fat Greek-style yogurt (plain and flavored) compared with whole milk Greek-style yogurt (plain and flavored, respectively) • Low-fat cottage cheese (1% and 2% milk fat) compared with creamed (4% milk fat) cottage cheese • Reduced-fat cheeses compared to full-fat cheeses • Part-skim mozzarella compared with whole milk mozzarella

1. If the food bearing the claim exceeds the disclosure levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per RACC, per labeled serving or per 50 g (as appropriate for a RACC that is less than or equal to 30 g or 2 Tablespoons) — 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 (saturated fat) than our regular Swiss cheese. Fat (saturated 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. Must also display the PUFA and MUFA quantities within the Nutrition Facts label because this is a fatty-acid claim.

a. On products intended for adults and children 4 years and over.

b. Required Statements

150 21 CFR 101.62 (c)(1)
151 21 CFR 101.62 (c)(2)
152 21 CFR 101.62 (c)(4)
153 21 CFR 101.13(j)

APPENDIX *(CONTINUED)*

TABLE 15
Cholesterol claims

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Cholesterol-free[154]	• *Free of cholesterol* • *Zero cholesterol* • *Without cholesterol* • *No cholesterol* • *Trivial source of cholesterol* • *Negligible source of cholesterol* • *Dietarily insignificant source of cholesterol*	For foods that contain 13 g or less of total fat per RACC, per labeled serving size and (if a small RACC) per 50 g: Contains less than 2 mg of cholesterol per RACC and per labeled serving size. Contains 2 g or less of saturated fat per RACC. For foods that contain more than 13 g total fat per RACC, per labeled serving size and (if a small RACC) per 50 g: Contains less than 2 mg of cholesterol per RACC and per labeled serving size. Contains 2 g or less of saturated fat per RACC. Discloses the quantity of total fat per serving adjacent to the cholesterol-free claim. In both scenarios, the food contains no ingredient that is generally understood by consumers to contain cholesterol unless the ingredient, as declared in the ingredient list, is accompanied by an asterisk (*) that refers consumers to the statement **Adds a trivial amount of cholesterol.* or similar specified statement. If the food is specially processed to achieve this nutrient level, and the product has 5% or more market share, additional declarations for relative claims are required—see regulations for extensive detail.[155]	1, 3, 5	• orange sherbet
Low cholesterol[156]	• *Low in cholesterol* • *Contains a small amount of cholesterol* • *Low source of cholesterol* • *-little cholesterol*	Maximum of 20 mg cholesterol per RACC. (When RACC is 30g or less, or ≤ 2 tbsp, it has to meet these requirements per 50 g of food). AND--Maximum 2 g saturated fat per RACC (When RACC is 30g or less, or ≤ 2 tbsp, it has to meet these requirements per 50 g of food). If product is not processed to meet criteria, disclose if "low cholesterol" criteria is true of all foods in category (e.g., a low cholesterol food). If the food is specially processed to achieve this nutrient level, and the product has 5% or more market share, additional declarations for a relative claim are required—see regulations for extensive detail.[157]	1, 3, 4, 5	• Skim milk • Low-fat milk (plain and flavored) • (1% milk fat) • Fat-free yogurt • Low-fat yogurt (plain and flavored) • Low-fat cottage cheese (1% and • 2% milk fat) • Fat-free cheeses • Low-fat swiss cheese

154 21 CFR 101.62 (d)(1)
155 21 CFR 101.62 (d)(1)(i)
156 21 CFR 101.62 (d)(2)
157 21 CFR 101.62 (d)(2)

APPENDIX *(CONTINUED)*

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Reduced cholesterol[158]	• *Reduced in cholesterol* • *Cholesterol reduced* • *Lower cholesterol* • *Less cholesterol*	At least a 25% reduction in cholesterol per RACC in comparison to an appropriate reference food[159] and contains 2 g or less of saturated fat per RACC. (When RACC is 30g or less, or ≤ 2 tbsp, it has to meet these requirements per 50 g of food). Claim not permitted if the reference (comparison) food meets the definition of "low cholesterol" claim. If the food is specially processed to achieve this nutrient level, and the product has 5% or more market share, additional declarations for a relative claim are required—see regulations for extensive detail.[160]	1, 2, 4, 5	• Low fat plain Greek-style yogurt compared with whole milk Greek-style yogurt • Low-fat cottage cheese (1% and 2% milk fat) compared with creamed (4% milk fat) cottage cheese

*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 for a RACC that is less than or equal to 30 g or 2 Tablespoons) — 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.
5. Must also display the PUFA and MUFA quantities within the Nutrition Facts label when a claim is made for fatty acids or cholesterol.

158 21 CFR 101.62(d)(4)
159 21 CFR 101.13(j)
160 21 CFR 101.62 (d)(4)

APPENDIX *(CONTINUED)*

TABLE 16
Sodium claims

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Sodium free[161]	• Free of sodium • No sodium • Zero sodium • Without sodium • Trivial source of sodium • Salt free[162]	Less than 5 mg sodium per RACC (regardless of RACC size) and per labeled serving size. The food contains no ingredient that is generally understood by consumers to contain sodium unless the ingredient, as declared in the ingredient list, is accompanied by an asterisk (*) that refers consumers to the statement **Adds a trivial amount of sodium. or similar specified statement.* *NOTE: "No salt added" and "Unsalted" must declare "this is not a sodium free food" on information panel if food is not "Sodium free."*	1, 3	
Very low sodium[163]	• *Very low in sodium*	Maximum of 35 mg of sodium per RACC. (When RACC is 30g or less, or ≤ 2 tbsp, it has to meet these requirements per 50 g of food).	1, 3	• Light whipping cream • Heavy cream
Low sodium[164]	• *Little sodium* • *Low source of sodium* • *Contains a small amount of sodium* • *Low in sodium*	Maximum of 140 mg of sodium per RACC. (When RACC is 30g or less, or ≤ 2 tbsp, it has to meet these requirements per 50 g of food).	1, 3	• All fluid white milk • Plain, flavored, and Greek yogurt • Sour cream • Ice cream • Orange sherbet • Half-and-half • Swiss cheese (regular and low-fat) • Ricotta cheese (whole milk and part-skim)
Reduced in sodium[165]	• *Reduced sodium* • *Sodium reduced* • *Less sodium* • *Lower sodium* • *Lower in sodium*	At least a 25% reduction in sodium per RACC in comparison to an appropriate reference food.[166] Claim cannot be made if comparison food meets definition for "low sodium."	1, 2	• Some reduced sodium cheeses
Light in sodium[167]	• *Lite* • *Light*	Condition #1: Reference food contains both less than 40 calories and less than 3 grams fat per RACC Product is reduced in sodium by 50% or more per matching RACC of an appropriate reference food.[168] 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*, or *light in sodium Pasteurized process American cheese.*

161 21 CFR 101.61 (b)(1)
162 21 CFR 101.61 (c)(1)
163 21 CFR 101.61 (b)(2)
164 21 CFR 101.61 (b)(4)
165 21 CFR 101.61 (b)(6)
166 21 CFR 101.13(j)
167 21 CFR 101.56 (c)(1) and (c)(2)
168 21 CFR 101.13(j) and 101.56(c)(2)(iii). The reference food: (1) must be the same type of food (e.g., cottage cheese compared to cottage cheese); (2) have a sodium content that represents that type of food

APPENDIX *(CONTINUED)*

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Light in sodium[169]	• *Lite in sodium* • *Light in sodium*	Condition #2: Reference food contains either more than 40 calories or more than 3 grams of fat per RACC. Product is reduced in sodium by 50% or more per matching RACC of an appropriate reference food.[170] 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*, or *light in sodium Pasteurized process American cheese*.

*Required Statements

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.[170]

1. If the food bearing the claim exceeds the disclosure 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 for a RACC that is less than or equal to 30 g or 2 Tablespoons) — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): S*ee nutrition information for [nutrient(s) requiring disclosure] content.*
2. For relative claims only: In addition to a disclosure statement identifying nutrients (see #1 above, 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 sodium than our regular Swiss cheese. Sodium has been reduced from 200 mg to 150 mg 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.*

169 21 CFR 101.13(j) and 101.56(c)(2)(iii). The reference food: (1) must be the same type of food (e.g., cottage cheese compared to cottage cheese); (2) have a sodium content that is representative of that type of food (e.g., the reference food sodium content could be that listed in the USDA National Nutrient Database for Standard Reference data for cottage cheese; (3) cannot qualify as a low sodium food.

170 21 CFR 101.61 (c)

APPENDIX *(CONTINUED)*

TABLE 17
Sugar claims

The following nutrient content claims are permitted by regulation. Sugar means the ingredient cane sugar or beet sugar when it appears with the ingredient list. *Sugars* also refers to the nutrients chemically identified as mono- and di-saccharides that are indented values beneath Total Carbohydrate on the Nutrition Facts label.

Unless dairy products are processed to reduce lactose, use claims that are truthful and non-misleading when describing dairy products and the absence of sugar(s). See "Lactose-free" section on page 38.

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Sugar free[171]	• *Free of sugar* • *No sugar* • *Zero sugar* • *Without sugar* • *Sugarless* • *Trivial source of sugar* • *Negligible source of sugar* • *Dietarily insignificant amount of sugar*	The food contains less than 0.5 g sugars per RACC and per labeled serving. The food contains no ingredient that is generally understood by consumers to contain sugar unless the ingredient, as declared in the ingredient list, is accompanied by an asterisk (*) that refers consumers to the statement **Adds a trivial amount of sugar.* or similar specified statement. The food is labeled *Low Calorie* or *Reduced Calorie,* or else the *sugar free* claim must be accompanied by *not a low calorie food,* or *not a reduced calorie food,* or *not for weight control* statement.	1, 3, 4	• Most cheeses
No added sugar[172]	• *Without added sugar* • *No sugar added*	No amount of sugars or ingredient that contains sugars is added during processing or packaging. The food does not contain an ingredient containing added sugars. The sugars content of the food has not been increased by some means such as the use of enzymes, unless a functionally insignificant increase in sugar results. The food for which the *no sugar added* food is a substitute normally contains added sugar. The food is either a *Low Calorie* or *Reduced Calorie* food or bears a *not a low calorie food* (or *not a reduced calorie food*) statement, AND — a statement to *see nutrition information for further information on sugar and calorie content.*	1	

171 21 CFR 101.60 (c)(1)
172 21 CFR 101.60 (c)(2)

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Reduced sugar[173]	• *Reduced in sugar* • *Sugar reduced* • *Less sugar* • *Lower sugar* • *Lower in sugar*	The food contains at least 25% less sugar per RACC in comparison to an appropriate reference food.[174]	1, 2	• Some formulated flavored milk and/or yogurts may qualify

*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 for a RACC that is less than or equal to 30 g or 2 Tablespoons) — 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 sugar than our regular strawberry flavored skim milk. Sugar has been reduced from 8 g to 6 g per 1 cup serving.*
3. If the food contains an ingredient generally understood by consumers to contain sugar, the listing of that ingredient in the Ingredient List must have an asterisk referencing an **adds a negligible amount of sugar* statement that follows the ingredient list. Fruit juices and purees are considered a source of added sugars.[175]
4. If the food has not been specially processed or formulated to remove sugar, the claim must be accompanied by the statement, *a sugar-free food.*

173 21 CFR 101.60 (c)(5)
174 21 CFR 101.13(j)
175 U.S. Food & Drug Administration. Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm535371.htm.

APPENDIX *(CONTINUED)*

TABLE 18
Calorie claims

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Calorie free[176]	• *No calories* • *Zero calories* • *Free of calories* • *Without calories* • *Trivial source of calories* • *Negligible source of calories* • *Dietarily insignificant source of calories*	The food contains less than 5 calories per RACC and per labeled serving.	1, 3	
Low calorie[177]	• *Few calories* • *Contains a small* • *amount of calories* • *Low source of calories* • *Low in calories*	40 calories or less per RACC. (When RACC is 30 g or less, or ≤ 2 tbsp, it must meet these requirements additionally per 50 g of food).	1, 3	
Reduced calorie[178]	• *Reduced in calories* • *Calorie reduced* • *Fewer calories* *-Lower calorie* *-Lower in calories*	The food contains at least a 25% calorie reduction per RACC in comparison to an appropriate reference food.[179] Cannot be made if comparison food meets the definition of *low calorie*.	1, 2	Products formulated using less sugar and fat may quality, such as reformulated: • Ice cream • Yogurts • Frozen yogurts • Flavored milk

*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 for a RACC that is less than or equal to 30 g or 2 Tablespoons) — 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% fewer calories than our regular Chocolate flavored frozen yogurt. Calories have been reduced from 250 g to 150 g per 2/3 cup 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. There are no relevant calorie free or low calorie claims for most dairy products.

176 21 CFR 101.60(b)(1)
177 21 CFR 101.60(b)(2)
178 21 CFR 101.60(b)(4)
179 21 CFR 101.13(j)

TABLE 19
Light or *Lite* claims

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATEMENTS*	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
Light[180] (For fat or calories. For *light in sodium* claim, see Table 16)	• *Lite* • *Light*	Condition #1: 50% or more of calories are from fat. Fat content must be reduced by at least 50% compared to a reference food.[181] This claim cannot be made if reference food meets definition of *low fat* and *low calorie*.	1, 2	Reformulated ice cream (i.e., frozen dairy desserts), yogurts and frozen yogurts using artificial sweeteners or fat substitutes
		Condition #2: less than 50% of calories are from fat. Fat content must be reduced by at least 50%; OR Calories must be reduced by at least 1/3, compared to a reference food.[182] This claim cannot be made if reference food meets definition of *low fat* and *low calorie*.	1, 2	Reformulated ice cream (i.e., frozen dairy desserts), yogurts and frozen yogurts using artificial sweeteners or fat substitutes

*Required statements

1. If the food bearing the claim exceeds the disclosure levels (Table 3 of this guide) of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount, per labeled serving, or per 50 g (as appropriate for a RACC that is less than or equal to 30 g or 2 Tablespoons) — 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* — 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 the leading Swiss cheese. Fat has been reduced from 8 g to 6 g, and calories have been reduced from 100 to 80 per serving.*

Note: 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*. Also, if a manufacturer can demonstrate through common use that the term *light* has been associated 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].

180 21 CFR 101.56(b)
181 21 CFR 101.13(j) and 101.56(c)(2)(iii). The reference food is to be similar food (e.g., regular potato chips as a reference food for fat-modified potato chips). The reference food nutrient values are to be representative of that type of food (e.g., values from a valid database).
182 21 CFR 101.13(j) and 101.56(c)(2)(iii). The reference food is to be similar food (e.g., regular potato chips as a reference food for fat-modified potato chips). The reference food nutrient values are to be representative of that type of food (e.g., values from a valid database).

APPENDIX *(CONTINUED)*

TABLE 20
Healthy claims

CLAIM	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITION AND CRITERIA	PARTIAL LIST OF ELIGIBLE DAIRY PRODUCTS
Healthy[183]	• *Health* • *Healthful* • *Healthfully* • *Healthfulness* • *Healthier* • *Healthiest* • *Healthily* • *Healthiness*	• Low-fat: <3 g fat per RACC (and per 50 g if the RACC is less than or equal to 30 g or 2 Tablespoons). – Unless the fat profile makeup is predominantly made up of MUFA + PUFA (then FDA will evaluate each claim at its discretion) • Low in saturated fat: <1 g per RACC and <15% of calories from saturated fats • Sodium: <480 mg per RACC and per labeled serving • Cholesterol: <60 mg per RACC and per labeled serving • Without fortification or enrichment, contains at least 10% of the DRI or RDV per RACC for one or more of the following – Vitamin A, vitamin C, calcium, iron, protein, fiber, potassium, or vitamin D	• Low-fat cottage cheese (1% milk fat) • Fat-free milk • Fat-free yogurt

TABLE 21
Numeric declaration claims

NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITION	REQUIRED STATEMENTS*	PARTIAL LIST OF ELIGIBLE DAIRY PRODUCTS
Percent[184] (for vitamins and minerals excluding sodium and fluoride)	A statement that describes the percentage in relation to the RDI Percentage claims permitted as long as the nutrient is at least a "good source" of the nutrient (i.e., 10%DV or more per RACC)	1	• Cheddar cheese: *20% of the DV for calcium per serving* • Low-fat yogurt: *30% of the DV for calcium per serving* • Reduced-fat milk: *15% of the DV for protein per 1 cup*
Percent[185] (for ingredients with no RDI or DRV)	A statement that characterizes the percentage level of the dietary ingredient can be made if the actual amount of the dietary ingredient per serving is declared next to the percentage statement	1	• Formulated milk with added DHA: *___% omega-3 fatty acids, __mg per serving*

*Required statements

1. If the food bearing the claim exceeds the disclosure 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, per labeled serving, or per 50 g (as appropriate for a RACC that is less than or equal to 30 g or 2 Tablespoons) — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): *See nutrition information for [nutrient(s) requiring disclosure] content.*

183 21 CFR 101.65(d)(2); FDA Guidance. Use of the Term "Healthy" in the Labeling of Human Food Products: Guidance for Industry. September 2016
184 21 CFR 101.13(q)(3)
185 21 CFR 101.13(q)(3)(ii)(A)

APPENDIX *(CONTINUED)*

TABLE 22

Nutritional composition overview of select dairy foods[186]

DAIRY FOODS	US DEPARTMENT OF AGRICULTURE FOODDATA CENTRAL FDC #[a]	CALORIES (kcal)	TOTAL FAT (g)	SATURATED FAT (g)	TRANS FAT (g)	CHOLESTEROL (mg)	SODIUM (mg)	TOTAL CARBOHYDRATE (g)	TOTAL SUGARS (g)	DIETARY FIBER (g)	PROTEIN (g)	VITAMIN D (IU)[b]	CALCIUM (mg)	IRON (mg)	POTASSIUM (mg)	LACTOSE (g)
Milk Products per Serving Size 1 cup (244g)																
Whole, 3.25% milkfat, with added vitamin D	1077	149	7.93	4.54	n/a	24.4	105	11.7	12.3	0	7.69	124	276	0.073	322	12.3
Reduced fat, fluid, 2% milkfat, with added vitamin A and vitamin D	1079	122	4.83	3.07	0.207	19.5	115	11.71	12.3	0	8.05	120	293	0.049	342	12.2
Lowfat, fluid, 1% milkfat, with added vitamin A and vitamin D	1082	102	2.37	1.54	n/a	12.2	107	12.2	12.7	0	8.22	117	305	0.073	366	12.7
Nonfat, fluid, with added vitamin A and vitamin D (fat free or skim) 1cup (245g)	1085	83.3	0.196	0.137	n/a	4.9	103	12.2	12.5	0	8.26	115	299	0.073	382	12.5
Milk Products per Serving Size 1 cup (250g)																
Chocolate, fluid, commercial, whole, with added vitamin A and vitamin D	1102	208	8.47	5.25	n/a	30	150	25.8	23.8	2	7.92	128	280	0.6	418	n/a
Chocolate, fluid, commercial, reduced fat, with added vitamin A and vitamin D	1103	190	4.75	2.95	n/a	20	165	30.2	23.9	1.75	7.48	122	272	0.6	422	9.58
Chocolate, fat free, with added vitamin A and vitamin D	1292	168	0	0	0	5	198	33.8	21	0	8.48	105	318	0.675	455	n/a
Milk Products per Serving Size 1 cup (254g)																
Eggnog	1057	224	10.6	6.58	n/a	150	137	20.4	20.4	0	11.6	124	330	0.508	419	19.9
Cheese Products per Serving Size 4oz (113g)																
Cottage, creamed, large or small curd	1012	111	4.86	1.94	n/a	19.2	356	3.82	3.02	0	12.5	3.39	93.8	0.079	118	3.02
Cottage, lowfat, 2% milkfat	1015	91.5	2.56	1.4	0.076	13.6	348	5.38	4.52	0	11.8	0	125	0.147	141	4.37
Cottage, lowfat, 1% milkfat	1016	81.4	1.15	0.729	n/a	4.52	459	3.07	3.07	0	14	0	68.9	0.158	97.2	n/a
Cheese Products per Serving Size 4oz (113g)																
Cottage, creamed, large or small curd	1012	111	4.86	1.94	n/a	19.2	356	3.82	3.02	0	12.5	3.39	93.8	0.079	118	3.02
Cottage, lowfat, 2% milkfat	1015	91.5	2.56	1.4	0.076	13.6	348	5.38	4.52	0	11.8	0	125	0.147	141	4.37
Cottage, lowfat, 1% milkfat	1016	81.4	1.15	0.729	n/a	4.52	459	3.07	3.07	0	14	0	68.9	0.158	97.2	n/a

186 Fooddata Central Search Results, US Department of Agriculture (Agriculture Research Services). Data on food components, including nutrients, that are derived from analyses, calculations, and the published literature for a comprehensive list of foods. SR Legacy, released in April 2019. https://fdc.nal.usda.gov/fdc-app.html#/food-search

APPENDIX *(CONTINUED)*

TABLE 22
Nutritional composition overview of select dairy foods

DAIRY FOODS	US DEPARTMENT OF AGRICULTURE FOODDATA CENTRAL FDC #[a]	CALORIES (kcal)	TOTAL FAT (g)	SATURATED FAT (g)	TRANS FAT (g)	CHOLESTEROL (mg)	SODIUM (mg)	TOTAL CARBOHYDRATE (g)	TOTAL SUGARS (g)	DIETARY FIBER (g)	PROTEIN (g)	VITAMIN D (IU)[b]	CALCIUM (mg)	IRON (mg)	POTASSIUM (mg)	LACTOSE (g)
Cheese Products per Serving Size 1oz (28.35g)																
Cold Pack American	1045	93.8	6.95	4.37	n/a	18.1	274	2.36	n	0	5.58	n/a	141	0.238	103	n/a
Pasteurized process, American, vitamin D fortified	1046	93.6	7.26	4.28	0.26	27.8	363	2.43	1.58	0	4.79	28.9	193	0.074	72.3	1.53
American, nonfat, or fat free (19g)	1061	23.9	0	0	0	4.94	251	2	0.999	0	3.99	0.95	150	0	74.7	n/a
Blue	1004	353	28.7	18.7	n/a	75	1150	2.34	0.5	0	21.4	21	528	0.31	256	n/a
Brick	1005	105	8.42	5.33	n/a	26.6	159	0.791	0.145	0	6.58	6.24	191	0.122	38.6	n/a
Brie	1006	94.7	7.85	4.93	n/a	30	178	0.128	0.128	0	5.9	5.67	52.2	0.142	43.1	n/a
Camembert	1007	85	6.89	4.34	n/a	20.4	239	0.13	0.13	0	5.61	5.1	110	0.094	53	n/a
Caraway	1008	107	8.28	5.27	n/a	26.4	196	0.868	n	0	7.14	n/a	191	0.181	26.4	n/a
Cheddar, sharp, sliced	1270	115	9.46	5.43	0.33	27.7	180	0.596	0.076	0	6.78	11.5	199	0.045	21.3	0.05
Cheddar	1009	114	9.44	5.36	n/a	28.1	185	0.955	0.136	0	6.49	6.8	201	0.04	21.5	0.034
Cheddar, nonfat or fat free (28g)	1265	44	0	0	0	5.04	280	2	0	0	8.99	1.4	250	0	18.5	n/a
Low fat, cheddar or colby	1168	49	1.98	1.23	n/a	5.95	247	0.541	0.147	0	6.92	1.42	118	0.119	18.7	n/a
Cheddar, reduced fat (21g)	1260	66.4	4.28	2.65	0.154	16	132	0.561	0.055	0	5.75	2.73	160	0.025	13.2	0.038
Cheshire	1010	110	8.68	5.53	n/a	29.2	198	1.36	n/a	0	6.63	n/a	182	0.06	26.9	n/a
Colby	1011	112	9.1	5.73	n/a	26.9	171	0.729	0.147	0	6.75	6.8	194	0.215	36	n/a
Edam	1018	101	8.11	5.3	n/a	25.2	276	0.405	0	0	7.09	5.67	207	0.125	53.3	n/a
Feta	1019	75.1	6.1	3.77	n/a	25.2	323	1.1	0	0	4.03	4.54	140	0.184	17.6	n/a
Fontina	1020	110	8.82	5.44	n/a	32.9	227	0.439	0.439	0	7.26	6.52	156	0.065	18.1	n/a
Gjetost	1021	132	8.36	5.44	n/a	26.6	170	12.1	n/a	0	2.74	n/a	113	0.147	400	n/a
Goat, hard	1156	128	10.1	6.97	n/a	29.8	120	0.615	0.615	0	8.65	7.37	254	0.533	13.6	n/a
Goat, semi soft	1157	103	8.45	5.84	n/a	22.4	118	0.034	0.034	0	6.12	6.24	84.5	0.459	44.8	n/a
Goat, soft	1159	74.8	5.98	4.14	n/a	13	130	0	0	0	5.24	4.25	39.7	0.539	7.37	n/a
Gouda	1022	101	7.77	4.99	n/a	32.3	232	0.629	0.629	0	7.06	5.67	198	0.068	34.3	n/a
Gruyere	1023	117	9.16	5.36	n/a	31.2	202	0.102	0.102	0	8.45	6.8	286	0.048	23	n/a
Limburger	1024	92.7	7.71	4.73	n/a	25.5	227	0.139	0.139	0	5.67	5.67	141	0.037	36.3	n/a
Mexican blend (28g)	1251	108	8.99	4.51	n/a	26.6	170	0.036	0	0	6.58	5.88	185	0.165	23.8	0
Mexcian blend, reduced fat	1209	79.9	5.5	3.29	n/a	17.6	220	0.967	0.159	0	7	3.97	326	0.037	26.4	n/a
Mexican, queso anejo	1165	106	8.5	5.39	n/a	29.8	320	1.31	1.31	0	6.07	6.24	193	0.133	24.7	n/a
Mexican, queso asadero	1166	101	7.09	4.2	n/a	29.8	172	1.17	0	0	6.41	5.95	187	0.145	24.4	n/a
Mexican, queso chihuahua	1167	106	8.42	5.33	n/a	29.8	175	1.58	1.58	0	6.12	6.24	185	0.133	14.7	n/a

TABLE 22
Nutritional composition overview of select dairy foods

DAIRY FOODS	US DEPARTMENT OF AGRICULTURE FOODDATA CENTRAL FDC #[a]	CALORIES (kcal)	TOTAL FAT (g)	SATURATED FAT (g)	TRANS FAT (g)	CHOLESTEROL (mg)	SODIUM (mg)	TOTAL CARBOHYDRATE (g)	TOTAL SUGARS (g)	DIETARY FIBER (g)	PROTEIN (g)	VITAMIN D (IU)[b]	CALCIUM (mg)	IRON (mg)	POTASSIUM (mg)	LACTOSE (g)
Cheese Products per Serving Size 1oz (28.35g)																
Monterey, low fat (28g)	42155	87.6	6.05	3.92	n/a	18.2	219	0.196	0.157	0	7.9	4.48	197	0.202	22.7	n/a
Monterey	1025	106	8.59	5.42	n/a	25.2	170	0.193	0.142	0	6.95	6.24	211	0.204	23	n/a
Muenster, low fat (28g)	42303	75.9	4.93	3.08	n/a	17.6	168	0.98	0.98	0	6.92	3.64	148	0.115	37.5	n/a
Mozzarella, low moisture, part-skim	1029	83.6	5.61	3.2	0.204	18.1	189	1.58	0.539	0	6.75	4.25	198	0.062	53.3	0.318
Mozzarella, whole milk	1026	84.8	6.26	3.94	n/a	22.4	138	0.68	0	0	6.29	4.54	143	0.125	21.5	0
Mozzarella, part skim milk	1028	72	4.51	2.86	n/a	18.1	175	0.785	0.32	0	6.89	3.4	222	0.062	23.8	n/a
Muenster	1030	104	8.5	5.42	n/a	27.2	178	0.318	0.318	0	6.63	6.24	203	0.116	38	n/a
Neufchatel	1031	71.1	6.46	3.63	n/a	21	94.7	1.02	0.904	0	2.59	n/a	33.2	0.037	43.1	0.904
Pastuerized process, pimeto	1043	106	8.84	5.58	n/a	26.6	259	0.49	0.176	0.028	6.26	6.24	174	0.119	45.9	n/a
Provolone	1035	99.5	7.54	4.85	n/a	19.6	206	0.607	0.159	0	7.26	5.67	214	0.147	39.1	n/a
Provolone, reduced fate	1208	77.7	4.99	3.2	n/a	15.6	174	0.992	0.156	0	7	3.69	214	0.147	39.1	n/a
Parmesan, grated	1032	119	7.88	4.37	0.248	24.4	510	3.94	0.02	0	8.05	5.95	242	0.139	51	0
Parmesan, hard	1033	111	7.09	4.2	n/a	19.3	335	0.913	0.031	0	10.1	5.39	335	0.232	26.1	n/a
Parmesan, dry grated, reduced fat	1204	75.1	5.67	3.77	n/a	24.9	434	0.388	0	0	5.67	4.25	315	0.255	35.4	n/a
Port de salut	1034	99.8	8	4.73	n/a	34.9	151	0.162	0.162	0	6.75	5.95	184	0.122	38.6	n/a
Swiss	1040	111	8.79	5.16	0.28	26.4	53	0.408	0	0	7.66	0	252	0.037	20.4	0
Swiss, nonfat or fat free (28g)	1266	35.6	0	0	n/a	5.04	280	0.952	0.372	0	7.95	1.12	269	0.048	31.1	n/a
Swiss, low fat (28g)	43589	50.1	1.43	0.924	n/a	9.8	55.7	0.952	0.372	0	7.95	1.12	269	0.048	31.1	n/a
Ricotta, whole milk (100g)	1036	150	10.2	6.42	0.333	49	110	7.27	0.27	0	7.54	10	206	0.13	219	n/a
Ricotta, part skim milk	1037	39.1	2.24	1.4	n/a	8.79	28.1	1.46	0.088	0	3.23	1.7	77.1	0.125	35.4	n/a
Roquefort	1039	105	8.68	5.47	n/a	25.5	513	0.567	0	0	6.1	n/a	188	0.159	25.8	n/a
Cheese, cream	1017	99.2	9.75	5.73	0.332	28.6	89	1.56	1.07	0	1.74	0	27.5	0.031	37.4	1.07
Tilsit	1041	96.4	7.37	4.76	n/a	28.9	213	0.553	0	0	6.92	n/a	198	0.065	18.4	n/a
Cheese, romano	1038	110	7.63	4.85	n/a	29.5	405	1.03	0.207	0	9.02	5.67	301	0.218	24.4	n/a

APPENDIX *(CONTINUED)*

TABLE 22

Nutritional composition overview of select dairy foods

DAIRY FOODS	US DEPARTMENT OF AGRICULTURE FOODDATA CENTRAL FDC #[a]	CALORIES (kcal)	TOTAL FAT (g)	SATURATED FAT (g)	TRANS FAT (g)	CHOLESTEROL (mg)	SODIUM (mg)	TOTAL CARBOHYDRATE (g)	TOTAL SUGARS (g)	DIETARY FIBER (g)	PROTEIN (g)	VITAMIN D (IU)[b]	CALCIUM (mg)	IRON (mg)	POTASSIUM (mg)	LACTOSE (g)
Yogurt Products per Serving Size 6oz (170g)																
Yogurt, plain, whole milk	1116	104	5.52	3.57	n/a	22.1	78.2	7.92	7.92	0	5.9	3.4	206	0.085	264	n/a
Yogurt, plain, low fat	1117	107	2.64	1.7	n/a	10.2	119	12	12	0	8.92	1.7	311	0.136	398	n/a
Yogurt, plain, skim milk	1118	95.2	0.306	0.197	n/a	3.4	131	13.1	13.1	0	9.74	0	338	0.153	434	n/a
Yogurt, vanilla, low fat	1119	144	2.12	1.37	n/a	8.5	112	23.5	23.5	0	8.38	1.7	291	0.119	372	n/a
Yogurt, Greek, strawberry, lowfat	1284	178	4.37	2.72	0.126	20.4	56.1	20.9	19	1.7	13.9	0	150	0.119	219	4.03
Yogurt Products per Serving Size 7oz (200g)																
Yogurt, Greek, plain, lowfat	1287	146	3.84	2.46	0.12	20	68	7.88	7.12	0	19.9	0	230	0.08	282	5.84
Yogurt Products per Serving Size (100g)																
Yogurt, Greek, plain, whole milk	1293	97	5	2.4	0	13	35	3.98	4	0	9	0	100	0	141	n/a
Ice Cream Products per Serving Size (70g)																
Ice Cream Sandwich	1238	166	6	1.62	n/a	14.7	90.3	26	13	0	3	0	60.2	0.182	80.5	n/a
Ice Cream Products per Serving Size (100g)																
Ice Cream Bar, covered with chocolate and nuts	1300	303	25.8	15.9	0	56	56	11.9	10.8	1.1	5.62	9	90	1.21	304	n/a
Milk Shake, thick chocolate	1110	119	2.7	1.68	n/a	11	111	21.2	20.8	0.3	3.05	41	132	0.31	224	n/a
Milk Shake, thick vanilla	1111	112	3.03	1.89	n/a	12	95	17.8	17.8	0	3.86	48	146	0.1	183	n/a
Ice Cream sundae cone	1301	254	14	2.72	0	15	115	28.9	21.3	1	3	4	60	0.36	204	n/a
Ice Cream soft serve, chocolate	1236	222	13	7.46	n/a	91	61	22.2	21.2	0.7	4.1	29	131	0.21	177	n/a
Cream Products per Serving Size 1tbsp (12g)																
Cream, sour, cultured	1056	23.8	2.33	1.12	0.096	7.08	3.72	0.556	0.409	0	0.292	0	12.1	0.008	15	0.409
Cream, sour, reduced fat, cultured 1tbsp (15g)	1055	20.2	1.8	1.12	n/a	5.85	13.4	0.639	0.024	0	0.441	1.35	15.6	0.011	19.4	n/a
Cream Products per Serving Size 1tbsp (15g)																
Cream, half and half	1049	19.6	1.72	1.05	0.07	5.25	9.15	0.645	0.619	0	0.469	0.3	16	0.007	19.8	0.619
Cream, light, coffee cream	1050	29.2	2.86	1.53	0.094	8.85	10.8	0.549	0.55	0	0.444	6.6	13.6	0.007	20.4	0.55
Cream Products per Serving Size 1tbsp (3g)																
Cream, whipped, cream topping, pressurized	1054	7.71	0.666	0.414	n/a	2.28	0.24	0.375	0.24	0	0.096	0.48	3.03	0.002	4.41	n/a
Butter Products per Serving Size 1tbsp (14.2g)																
Butter, without salt	1145	102	11.5	7.17	n/a	30.5	1.56	0.009	0.009	0	0.121	0	3.41	0.003	3.41	n/a
Butter, salted	1001	102	11.5	7.3	0.466	30.5	91.3	0.009	0.009	0	0.121	0	3.41	0.003	3.41	n/a

APPENDIX *(CONTINUED)*

TABLE 22

Nutritional composition overview of select dairy foods

DAIRY FOODS	US DEPARTMENT OF AGRICULTURE FOODDATA CENTRAL FDC #[a]	CALORIES (kcal)	TOTAL FAT (g)	SATURATED FAT (g)	TRANS FAT (g)	CHOLESTEROL (mg)	SODIUM (mg)	TOTAL CARBOHYDRATE (g)	TOTAL SUGARS (g)	DIETARY FIBER (g)	PROTEIN (g)	VITAMIN D (IU)[b]	CALCIUM (mg)	IRON (mg)	POTASSIUM (mg)	LACTOSE (g)
Other Products 1 cup (245g)																
Buttermilk, fluid, whole	1230	152	8.11	4.66	n/a	27	257	12	12	0	7.86	127	282	0.073	331	n/a
Other Products 1 cup (306g)																
Milk, canned, condensed, sweetened	1095	982	26.6	16.8	n/a	104	389	166	166	0	24.2	18.4	869	0.581	1140	n/a
Other Products 1 cup (120g)																
Cream, fluid, heavy, whipping	1053	408	43.3	27.6	1.49	136	32.4	3.41	3.5	0	3.41	75.6	79.2	0.12	114	3.5
Other Products 1 cup (227g)																
Butter, salted	1001	1630	184	117	7.45	488	1460	0.136	0.136	0	1.93	0	54.5	0.045	54.5	n/a
Other Products 1 cup (240g)																
Cheese spread, cream cheese base	43276	708	68.6	43.2	n/a	216	1050	8.4	8.4	0	17	50.4	170	2.71	269	n/a
Cheese, cream, low fat	43274	499	40.1	24	n/a	130	761	16.2	7.92	0	18.8	26.4	355	0.408	593	7.92
Other Products 100g																
Cheese, cream, fat free	1186	105	1	0.644	n/a	12	702	7.66	5.48	0	15.7	0	351	0.19	278	4.84

a USDA Food Data Central, (2019). fdc.nal.usda.gov. Nutrient values presented are raw data that are provided as examples and should not be used for nutrition labeling.

b 1 International Unit (IU) Vitamin D = 0.025 Microgram (mcg) for cholecalciferol/ergocalciferol. https://dsid.od.nih.gov/Conversions.php

n/a = not available

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