Close up on Food Labels

Information for California Food Processors

California Department of Public Health, Food and Drug Branch August 2013

The goal of food labeling is to provide consumers with information that is factual and relevant about the products they consume. The food label allows consumers to compare one product to another, gives instructions for safe handling and storage, lists ingredients to help consumers select foods with ingredients they want or need to avoid, and identifies the firm responsible for the product in the case of a defect with the food.

Certain label information, such as the responsible firm's name and address and ingredient declaration, is **required**. Other label information, such as health claims and nutrient content claims, are **voluntary**. These label statements are based on the following statutes:

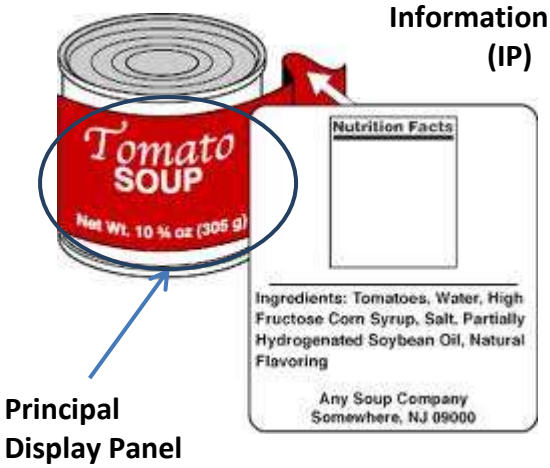
1. Fair Packaging and Labeling Act (FPLA) of 1967,
2. Federal Food, Drug, and Cosmetic Act (FD&C)
3. Nutrition Labeling and Education Act of 1990 (NLEA),
4. Dietary Supplement Health and Education Act of 1994 (DSHEA),
5. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and
6. Patient Protection and Affordable Care Act of 2010.

Label Panels

A food package usually has at least two distinct areas: the **Principal Display Panel** or **Primary Display Panel (PDP**) and the **Information Panel (IP).** The PDP is the part of the label consumers see first when selecting a food product. In most cases, the PDP is the front of the package that is likely to be seen during normal methods of display on store shelves. The IP is usually to the immediate right of the PDP (to the left, rear, top or bottom if there is insufficient space to the right of the PDP).

All required information on the label must be presented in a legible manner. It cannot be concealed in any manner such that it is unlikely for the consumer to read. The size of the lettering, unless stated, must be at least **1/16 inch** in height. Exceptions may be applied to small, single-serving packages as specified in 21 CFR §101.2. All required information must be in English. Accurately translated information in another language may accompany it.

Labels must be made of materials that do not contaminate the food. If there is likelihood that the paper, ink or adhesive of a label will touch the product or penetrate the packaging, these materials must be safe for food use.



Principal Display Panel (PDP) lists

- Product Name
- Net quantity of contents
- "Perishable Keep Refrigerated" (if applicable)
- "Made in a Home Kitchen" (if applicable)

Information Panel (IP) lists:

- Nutrition Facts
- Ingredients list
- Name and Address of the responsible firm

Food Name

All foods must be named. This name, which is often called the "S**tatement of Identity,"** can be either the "common name" or a "fanciful name" of the food. If a fanciful name is used, it must be accompanied by a descriptive phrase at least ½ the type size of the product name. The name has to be truthful and must be presented in **bold type** on the PDP (21 CFR §101.3 (d)).

If it is a "flavored" product, it must state so (e.g., "cherry flavored" pie). If the flavor is not derived from a natural source, then it must indicate so (e.g., "artificial cherry flavored" pie). When appropriate, it must describe the form of the food too, such as "sliced peaches" or "whole peaches". A brand name can serve as the statement of identity if the name is commonly used and easily understood by consumers (e.g., Pepsi, Coca-Cola).

Responsible Firm

There must be a firm (manufacturer, packer or distributor) identified on the label as a responsible party. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for" or "distributed by"). The firm's name, city, state and zip code must be declared. If the firm is not listed in the current telephone guide for that city, the street address must also be listed.

Net Quantity

Every packaged food must declare its count, net weight (drained weight if appropriate) or volume. The net quantity refers only to the quantity of food in a package or container. It includes the weight of any liquid in which the food may be packed if the liquid is usually eaten. It does not include the weight of the container or wrappers.

It must be stated in both English (inches/pounds/fluid ounces) units and metric units (grams/liters). For example: Net Wt. 8 oz. (226 g).

Ingredients

All packaged foods composed of <u>two or more ingredients</u> are required to include an **ingredient list**. The ingredient statement must be legible and be correctly listed in **descending order of predominance by weight.** Ingredients must be listed by their common or usual names (e.g., sugar instead of sucrose). Certain ingredients require special declaration. The sub-ingredients of a food that is an ingredient in another food may be declared following the name of the ingredient. For example: enriched flour (wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid).

Foods with two or more discrete components (e.g., cherry pie that has filling and pie crust) may have a separate ingredient list for each of the components, or list all of them together under one list. For foods that are sold in bulk, a list of ingredients must be stated on a sign or on the food's original container. For more information, refer to 21 CFR § 101.4.

Product Dates / Lot Codes

Product dating is optional for most food products. There are two types of dating on food packaging: "open dating" and "lot coding".

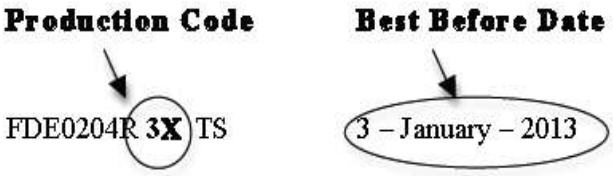
Open dating is recommended for all foods that are readily perishable. It:

- provides information in a conventional date format such as "July 10", or numerically such as "7-10" or "710;"
- includes "pull date," "quality assurance or freshness date", "pack date" and "expiration date." Manufacturers have the pull date, quality assurance date or pack date on labels to inform retailers and consumers when the product was made or how long their products should be offered for sale to ensure optimum quality. An expiration date is the date before which a product should be eaten;

Certain foods, such as infant formula (21 CFR § 107.20) and dairy products (3 CCR § 627 must have an expiration (sell by or use by) date.

Lot codes make it easier for manufacturers to quickly identify, track down and remove a product from the market in the event of recall. It:

- provides information using letters, numbers and symbols;
- enables the manufacturer to convey a relatively large amount of information, such as production code and date, location of production and/or packaging.



Lot codes are not typically discernable to consumers since they do not have access to the breakdown of the code.

Nutrition Facts

Most processed and packaged foods (except exempt foods) must declare information about the foods' nutritional content using the correct typeface, font size, and formats approved by FDA for the "**Nutrition Facts"** panel as shown on this page.

Variations in the format and criteria for the variations are defined in 21 CFR §101.9. For instance, a simplified format is allowed when the food contains insignificant amounts of eight or more of the **mandatory nutrients** (Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugar, protein, vitamin A, vitamin, calcium, and iron), The **five core nutrients** (Calories, total fat, sodium, total carbohydrate, and protein) must appear on all "Nutrition Facts" panels regardless of the amount present in the food or the format used.

The amount of *trans* fat in a serving must be listed on a separate line under saturated fat on the "Nutrition Facts" panel as shown on the example on this page. However, *trans* fat does not have to be listed if the total fat in a food is less than **0.5 gram (or 1/2 gram)** per serving and no claims are made about fat, fatty acid or cholesterol content. If *trans* fat is not listed, a footnote must be added stating that the food is "**Not a significant source of *trans* fat."**

Insignificant Amounts

Amounts such as "less than 5 calories" or "less than 1 g" can be shown as zero on the Nutrition Facts panel.

The foods listed on the next page are exempt from the mandatory NLEA nutrition labeling requirements provided that they neither bear nutrition

information nor make nutrient content claims or health claims on their labels:

- food produced by small businesses (with fewer than 100 full-time equivalent employees and fewer than 100,000 units per product sold in the United States in the previous year); Refer to Small Business Nutrition Labeling Exemption Guidance
- food served in restaurants**;
- ready-to-eat food prepared on site and sold directly to consumers (e.g., delicatessen type food or bakery products);
- food sold by food service vendors and vending machines**;
- food shipped in bulk as long as it is not for sale in that form to consumers;
- medical food;
- food containing no significant amount of any nutrients (e.g., spices, tea, coffee).

Refer to 21 CFR § 101.9 for additional exemptions.

***In 2012, FDA proposed regulations to require chain restaurants and similar retail establishments with 20 or more locations to display calorie content information on menus and menu boards, drive-through menu boards and on signs next to foods on display; and vending machine operators with 20 or more vending machines to make calorie information for certain foods available. For more information, refer to New Menu and Vending Machines Labeling Requirements.*

Nutrient Content Claims

A "Nutrient Content Claim" is a word or phrase on a food package that makes a comment about the nutritional value of the food. Eleven (11) basic terms have been defined for several nutrients, and FDA has set conditions for the use of these terms. The terms are: ***free, low, reduced, fewer, high, less, more, lean, extra lean, good source, and light***. For example, the term "sodium free" means that the food contains less than 5 milligrams of sodium per serving of the food.

Among the 11 terms, "lean" used to be applicable only to specific foods, such as seafood, game meat products, and meal-type products. In January 2007, FDA expanded its definition to make it applicable to foods categorized as "mixed dishes not measurable with a cup" that meet certain criteria for total fat, saturated fat, and cholesterol content. Such foods include burritos, egg rolls, enchiladas, pizza, quiches, and sandwiches. For details, please refer to 21 CFR §101.13. Any time a nutrient content claim is made, a Nutrition Facts panel must be included regardless of exemptions.

Health Claims

A "**Health Claim"** is a food label message that describes the relationship between a food component, such as fat, calcium, or fiber, and a disease or health-related condition. FDA has approved various health claims based on extensive scientific evidence and defined conditions under which the claims can be used (e.g., sodium and hypertension, calcium and osteoporosis).

For more information, refer to 21 CFR § 101.72-101.83, the Label Claims or the Guidance for Industry: A Food Labeling Guide at the FDA website.

What is the Difference?

Nutrient Content Claim *indicates the nutritional value of the food.*
Health Claim *describes the relationship between a food component and a disease or health-related condition.*

Food Allergens

All food labels must identify in plain language whether the food contains any of **eight (8) major food allergens**: milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

There are two methods that may be used in declaring the food sources of allergens in packaged foods:

1) in a separate summary statement immediately following or adjacent to the ingredient list, or
2) within the ingredient list itself.

As of August 5, 2014, gluten-free regulations will go into effect in order to assist up to 3 million Americans who have celiac disease (an autoimmune disorder triggered by eating gluten) to better manage their health by eating a gluten-free diet. The regulations define the term "gluten-containing grain" to mean any one of the following grains (e.g., wheat, rye, barley) or their crossbred hybrids (e.g. triticale, which is a cross between wheat and rye). Under the regulation, a "gluten-free" label claim means:

A) That the food bearing the "gluten free" claim does <u>not</u> contain any of the following:
   a. An ingredient that is a gluten-containing grain (e.g. spelt wheat);
   b. An ingredient derived from a gluten-containing grain and that has not been processed to remove gluten (e.g. wheat flour); or
   c. An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g. wheat starch), if the use of that ingredient results in the presence of 20 parts per million or more gluten in the food; or

B) The product inherently does not contain gluten; and any unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 parts per million gluten (21 CFR § 101.91).

Juice Products

The regulations (21 CFR § 120.1-120.25) require that all juice processors produce juice products under the **Hazard Analysis and Critical Control Point (HACCP)** principles to improve the safety of juice, which is sold as such or used as an ingredient in beverages.

Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. For beverages containing less than 100 percent juice, only the juice ingredient must comply with HACCP principles. All beverages containing juice must declare the **percent of total juice** on the Information Panel.

If the label of a multi-juice beverage names one or more juices and the named juices are present in minor amounts, it may either state the beverage is flavored by the named juice, such as "raspberry flavored juice drink," or declare the amount of the named juice in a 5 percent range, as "juice blend, 2 to 7 percent raspberry juice."

A warning statement shown below is required for juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens (21 CFR § 101.17);

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

This warning statement is only allowed in specific instances, such as when the juice is prepared at the retail venue where it is sold directly to the consumer (e.g., roadside apple cider stands.)

Refrigerated Foods

California law requires that all *Potentially Hazardous Foods (PHF)* have the statement **"Perishable Keep Refrigerated"** on the label in a conspicuous location, normally on the PDP. PHF is defined as food that is capable of supporting growth of infectious or toxigenic microorganisms when held at temperatures above 45^{o}F.

What are Potential Hazardous Foods (PHF)?

Foods that require time or temperature control to limit pathogenic micro-organism growth or toxin formation.

The statement "**Perishable Keep Frozen**" is also acceptable on the label of foods that are kept frozen.

Confectionery Products Containing Alcohol

Confectionery products are food items that are sweetened with sugar or sweeteners, such as candies, chocolates, and sweets. If a confectionery product contains alcohol in excess of **½ of 1 percent by weight**, that fact must be stated on the label for the food. If a facility sells directly to consumers such confectionery products that are unpackaged or unlabeled, the facility owner must provide a written notice to consumers of such fact (H&SC § 110695). Confectionery products must not contain any alcohol in excess of 5 percent by weight (H&SC § 110590).

Organic Foods

Foods represented as "organic" must meet the requirements of the USDA National Organic Program (NOP) Regulations and the California Organic Products Act of 2003. Products may be labeled as "100% organic" or "organic" if they are comprised of 100% certified organic ingredients or 95% certified organic ingredients, respectively (minus water and salt). Products containing between 70% and 95% certified organic ingredients may make a "**Made with Organic**" claim on their label.

Products labeled as "Organic" must be certified by a third party accredited certifying organization, and that organization's name must appear on the information panel of the organic food product. For additional organic labeling information, visit the NOP website at www.ams.usda.gov/nop

Safe Handling Statements

Raw meat and poultry products (e.g., fresh and frozen) including shell eggs must display safe handling instructions, as shown below, on their labels. The handling instructions should address safe storage of raw product, prevention of cross-contamination, cooking of raw product, and/or handling of leftovers. For example:
all shell eggs that have not been treated to prevent *Salmonella* before distribution to consumers must display the statement on the label according to the requirements in 21 CFR § 101.17(h)). See sample below

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cooked eggs until yolks are firm, and cook food containing eggs **thoroughly.**

The statement must appear on the label prominently and in a font size no smaller than 1/16th of an inch. The statement must appear in a hairline box and the words "safe handling instructions" appear in bold capital letters.

Warning Notices

Federal and state labeling regulations require certain foods and packages to declare warning notices. Examples of such products required by the federal regulation (21 CFR § 101.17) include:

- Protein product that derives more than 50 percent of total caloric value from either whole protein, protein hydrolysates, and/or amino acid mixtures, and that is represented for use in reducing weight;
- Dietary supplements containing iron or iron salts;
- Foods containing psyllium husk;
- Self-pressured containers or self-pressured containers with halocarbon or hydrocarbon propellants;
- Products containing substances that have stimulant laxative effects (17 CCR § 10750).

> "NOTICE: This product contains [name of substance(s) that can have stimulant laxative effects and common name(s) if different]. Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools, or abdominal pain. Consult your physician if you have frequent diarrhea, or if you are pregnant, nursing, taking medication, or have a medical condition."

California regulation requires the following products to carry warning notices. For example:

- Raw milk and raw milk products (17 CCR § 11380):

> "NOTICE: This product has not been pasteurized and, therefore, may cause serious illness in children, the elderly and persons with weakened immune system."

Bottled Water

In addition to basic label requirements, California law (H&SC § 111170 (f)) requires that bottled water labels declare all of the following:

- the name and contact information for the bottler;
- the source of the bottled water (unless treated to purified water standards);
- a clear and conspicuous statement that informs consumers how to access water quality information.

Bottled water must be named in accordance with the naming conventions in the standards of identity for bottled water in 21 CFR § 165.

Cottage Foods

In September 2012, the Homemade Food Act was signed into law by Governor Brown. Effective January 1, 2013, this law allows certain non-potentially hazardous foods to be made, packaged, stored or handled in private residential kitchens that received a registration or permit from a local county health department.

Cottage foods must comply with food labeling requirements and additionally must state:

1. "**Made in a Home Kitchen**" in 12-point type on the cottage food products' Primary Display Panel (PDP).

2. The registration or permit number of the "Class A" or "Class B" cottage food operation which produced the cottage food product and, in the case of a "Class B" cottage food operation, the name of the county of the local enforcement agency that issued the permit number.

For more information on the labeling requirements for cottage food products, refer to California Health and Safety Code § 114365.2(e).

Refer to the next page for an example of a Cottage Food Label.

Chocolate Chip Cookies
Sally Baker
123 Cottage Food Lane
Anywhere, CA 90XXX

Ingredients: Enriched flour (wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid), butter (milk, salt), chocolate chips (sugar, chocolate liquor, cocoa butter, butterfat (milk), soy lecithin, walnuts, sugar, eggs, salt, artificial vanilla extract, baking soda.

Contains: Wheat, eggs, milk, soy, walnuts

MADE IN A HOME KITCHEN
Permit #: 12345
Issued in county: County name

Dietary Supplements

Dietary supplements are regulated differently than conventional foods. Dietary supplements must be labeled according to the Dietary Supplement Health and Education Act (DSHEA) of 1994 and California Code of Regulations, Title 17, Sections 10200 and 10750.

A dietary supplement is defined as a product that contains one or more dietary ingredients, such as vitamins, minerals, herbs or botanicals, and amino acids in various forms (e.g., capsules, powders, soft gels, gel caps, tablets or liquids) that are intended to supplement the diet. Dietary supplements are prohibited from being sold for the treatment, prevention or cure of disease.

Manufacturers must declare the following information on the label;

1) Statement of identity;
2) Net quantity of contents;
3) Name and address of the manufacturer; packer or distributor
4) "Supplement Facts" panel;
5) Directions for use;
6) A list of ingredients not included the Supplement Facts panel. The ingredients must be listed in descending order of predominance and by common name or proprietary blend;
7) Include the following 'disclaimer' statement **if a structure or function claim is used.**

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease."

These regulations also set parameters for use of the terms "high potency" and "antioxidant," and for making "structure or function" claims. Structure or function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans (e.g., calcium supports building strong bones). Under DSHEA, structure and function claims may be used as long as such statements do not claim to diagnose, mitigate, treat, cure, or prevent disease and are not false or misleading.

A sample "Supplement Facts" panel is shown on below, however variations of formats may be allowed under certain circumstances. For more information, refer to 21 CFR § 101 or Dietary Supplements Labeling Guide at the FDA website.

Supplement Facts
Serving Size: 8.4 fl. oz.
Servings Per Container: 1 per can

Amount per Serving	% Daily Value
Calories 80	
Total Fat 0g	0%*
Total Carbohydrate 20g	7%*
Sugars 20g	
Sodium 0mg	0%
Proprietary blend 1830mg	
Choline (A-Glyceryl Phosphoryl Choline)	**
Eleutherococcus Extract (Root)	**
Rhodiola Rosea Extract (Root)	**
DMAE (as Dimethylaminoethanol)	**
Blue Green Algae (Plant)	**

** Daily Value not established.
* Daily Values based on a 2,000 calorie diet.

Other Ingredients: Carbonated Water, Organic Agave Nectar, Natural Flavors, Citric Acid.

Questions and Assistance

If you have questions about labeling laws and regulations or feel that a label is misleading, please contact us at FDBInfo@cdph.ca.gov . Please note that FDB does not approve labels. It is the responsibility of the firm identified on the label to make sure that the information on its label is accurate, truthful, and in compliance with pertinent laws and regulations.

For designing, formatting and proofing labels, a competent "food label consultant" should be consulted. A list of food label consultants in your area may be obtained by contacting trade organizations for food or the Institute of Food Technologists.

For questions regarding the labeling of foods containing more than 3 percent meat or poultry products, please contact the USDA-FSIS Meat and Poultry Hot Line at http://askkaren.gov or its Western Region offices.

For labeling information of imported or exported foods, you may contact the FDA. The California Department of Food and Agriculture, Milk and Dairy Food Safety Branch provide labeling information on milk and dairy products.

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Other Regulatory Agencies

FDA, San Francisco District
Office, Compliance Branch
1431 Harbor Bay Parkway Alameda, CA
94502-7070
(510) 337-6700

FDA, Los Angeles District
Office, Compliance Branch
19701 Fairchild
Irvine, CA 92612
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USDA-FSIS, Meat and Poultry
Hot Line 1-888-MPHotline (674-6854)
Email: mphotline.fsis@usda.gov

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California Department of Food and Agriculture
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(916) 900-5008

References

1. California Health and Safety Code (H&SC) Sections 110290, 110590,110660, 110695, 111170
2. California H&SC §113700 – 114437 “California Retail Food Code“
3. Food and Drug Administration (FDA). Guidance for Industry: A Food Labeling Guide
4. FDA Dietary Supplements Labeling Guide
5. FDA Small Business Nutrition Labeling Exemption Guidance
6. FDA New Menu and Vending Machine Labeling Requirements
7. FDA Dietary Supplement Health and Education Act 1994
8. Title 17, California Code of Regulations (CCR) Sections 10200 and 10750 “Dietary Supplement”
9. Title 17 CCR §11380 “Raw Milk”
10. Title 21, CFR Part 101, “Food Labeling”
11. Title 21 CFR Section 107.20 “Infant Formula”
12. Title 21, CFR Part 111, “Dietary Supplements”
13. Title 21, CFR Part 120 “ Hazard Analysis and Critical Control Points System (HACCP)”
14. Title 21 Code of Federal Regulations (CFR) § 165 “Bottled Water”
15. National Organic Program www.ams.usda.gov/nop
16. Cottage Foods Program Cottage Food