

Basic Labeling Requirements

Labeling is mandatory for all packaged foods. Packaged food must be labeled with the Statement of Identity, Ingredients, Allergens, Net Content, Business Name & Address, and, if applicable, a Nutrition Facts Panel. Accurate food labels are an important aspect of food safety, both for your customers and for your business. Undeclared allergens on food labels are the leading cause of food recalls in the U.S. This guidance document provides an overview of basic labeling requirements. Please see [21 CFR 101 Food Labeling](#) and the [Food and Administration's Food Labeling Guide](#) for additional information.

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I. Statement of Identity/Common Name of the Food



- Must be on the Principal Display Panel (Front Panel) if more than one panel is used.
- Must be an accurate description of the product.
- Must be prominent on the label.

II. Net Content Statement



- Must be on the Principal Display Panel (Front Panel) if more than one panel is used.
- Must be located on the bottom third of the panel.
- Must be stated in both standard and metric units.
- For liquid products:
 - Declared in fluid measure
 - May be preceded by "Net"
- For solid products:
 - Declared by weight
- Must be preceded by "Net Weight" or "Net Wt."

III. Ingredient Statement

Ingredients: Enriched Corn Meal (Corn Meal, Ferrous Sulfate, Niacin, Thiamin Mononitrate, Riboflavin, Folic Acid), Vegetable Oil (Corn, Canola, and/or Sunflower Oil), Cheese Seasoning (Whey, Cheddar Cheese [Milk, Cheese Cultures, Salt, Enzymes], Canola Oil, Maltodextrin [Made from Corn], Natural and Artificial Flavors, Salt, Whey Protein Concentrate, Monosodium Glutamate, Lactic Acid, Citric Acid, Artificial Color [Yellow 6]), and Salt.

- Must appear on the same panel as the name and address of your business.
- Ingredients must be listed in order of heaviest to lightest by weight.
- Some ingredients consist of multiple ingredients; these sub-ingredients must be listed in parentheses next to the main ingredient.
- There cannot be intervening material between the ingredient statement, business information, and nutrition facts statement.

IV. Allergens

Allergens within Ingredient List*

Ingredients: all-purpose flour (bleached **wheat** flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, **soy** lecithin, vanillin, natural flavor), butter (cream (**milk**), salt), **walnuts**, granulated sugar, brown sugar (molasses), **eggs**, sodium bicarbonate, vanilla extract (vanilla bean extractives in water, alcohol), salt.

OR

Allergens in Contains Statement*

Ingredients: all-purpose flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, soy lecithin, vanillin, natural flavor), butter (cream (milk), salt), walnuts, granulated sugar, brown sugar (molasses), eggs, sodium bicarbonate, vanilla extract (vanilla bean extractives in water, alcohol), salt.

Contains: wheat, soy, milk, walnuts, eggs

- When a major food allergen is an ingredient or sub-ingredient, it must be identified by name, either within the ingredient statement **OR** in a separate statement directly below the ingredient statement called a “contains statement”.
- The contains statement must only begin with “Contains:”.
- The only words that may be used to identify the allergens are the following:
 - Crustacean Shellfish (name the specific species of crustacean)
 - Eggs
 - Fish (name the specific species of fish)
 - Milk (specify if the milk is from another ruminant species other than cow, such as goat or sheep)
 - Peanuts
 - Sesame
 - Soybeans
 - Tree Nuts (name the specific type of nut)
 - Wheat

* Text does not need to appear in red

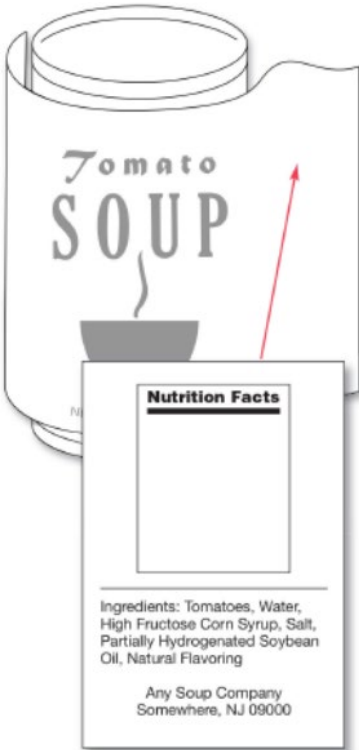
V. Name and Address of Manufacturer, Packer, or Distributor

MANUFACTURED BY:

Naturally Wholesome Foods, LLC
123 Healthy Way, Austin, TX 78701
www.naturallywholesome.com

- Must appear on the same panel as the ingredient statement.
- The address of the business must be listed in full: street name, city, state and zip. A Post Office Box number, telephone number, email address, website address, or other address cannot substitute.
 - The only exception would be if your business and address are listed in a current physical city or telephone directory.
 - In that case, you may omit the street address and list just the city, state, and zip code.
- There cannot be intervening material between the ingredient statement, business information, and nutrition facts statement.

VI. Nutrition Facts Panel



- Must appear on the same panel as the business name and address.
- Must be enclosed in a hairline box.
- Required if a Nutrient Content Claim appears on the label.
 - Examples: Low Fat, Sugar Free, Reduced Sodium
- There cannot be intervening material between the ingredient statement, business information, and nutrition facts statement.
- If you are interested in nutrition labeling, there are several options and providers you may choose from that can create a panel for you. For example, the [Food Producer Technical Assistance Network](#).
- Nutrition Labeling Exemptions
 - **Small Business Exemption** – this exemption applies if the person claiming the exemption employs fewer than an average of **100 full-time equivalent employees** and **fewer than 100,000 units** of that product are sold in the United States in a 12-month period. The company must file an annual notice with FDA to claim this exemption.
 - **Very Small Retailer Exemption** – this exemption applies for retailers with annual gross sales of **\$500,000 or less**, or annual sales of food directly to consumers of **\$50,000 or less**. A notice does not need to be filed for this exemption.
- **NOTE:** these exemptions do not apply if there are nutrient content claims on the label.

VII. Label Format

Your label may consist of **ONE** panel or **TWO** panels. An example of each is provided below.

One Panel Label

CHOCOLATE CHIP COOKIES

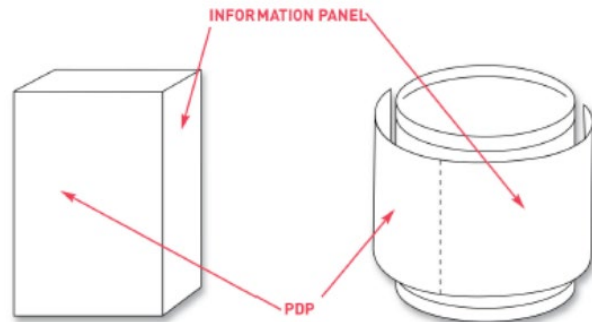
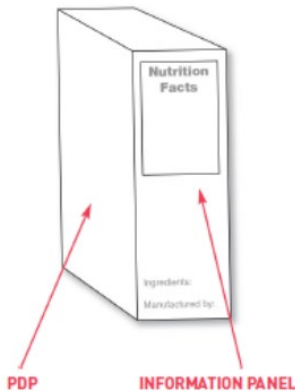
Ingredients: all purpose flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, soy lecithin, vanillin, natural flavor), brown sugar (molasses), sugar, walnuts, butter (cream, salt), eggs, salt, baking soda, vanilla extract (vanilla bean extractives in water, alcohol). **Contains: wheat, soy, milk, walnuts, eggs**

Grannie's Cookies, 111 Happy Lane, Anytown, VA 22554

Net Wt. 10 oz (283 g)

- The label must include the following:
 - Statement of Identity/Common Name
 - Net Content Statement
 - Ingredient Statement
 - Name and Address of Manufacturer/Packer/Distributor
 - Nutrition facts panel, if applicable

Two Panel Label



Panel One	Principal Display Panel (PDP) Front Panel	• Statement of Identity/Common Name • Net Content Statement
Panel Two	Information Panel Panel to the Right of the Front Panel	• Ingredient Statement • Name and Address of Manufacturer/Packer/Distributor • Nutrition facts panel, if applicable • No intervening material between required information • Must be to the right of the PDP

VIII. Labeling Claims

There are three categories of claims that are defined by statute and/or FDA regulations for use on food and dietary supplement labels: health claims, nutrient content claims, and structure/function claims.

1. Health Claims

- Health claims require a Nutrition Facts panel on the product label.
- A “health claim” has two essential components:
 - A substance (whether a food, food component, or dietary ingredient) and
 - A disease or health-related condition
- Health claims must:
 - Limit wording to disease or health-related condition risk reduction
 - Cannot suggest diagnosis, cure, mitigation, or treatment of a disease
 - Be evaluated and authorized by the FDA
- Information on authorized health claims may be found on the FDA’s [website](#).
- Examples:
 - “Eating at least 3 oz. of whole grains per day may reduce the risk of heart disease”



2. Nutrient Content Claims

- Nutrient content claims require a Nutrition Facts panel on the product label.
- A “nutrient content claim” characterizes the level of a nutrient in a food using terms such as “free”, “high”, “lite”, “low”, or “reduced”.
 - Nutrient content claims must:
 - Describe the level of nutrients in the product
 - Meet the nutritional criteria for that statement or a disclosure statement must be used if the claim is quantitative
 - Be authorized by the FDA
 - Be provided with a Daily Value if core descriptors are used (i.e., low sodium)
- Unless specifically authorized, nutrient content claims cannot be used for food intended for infants.
- Examples of the conditions for several nutrient content claims are provided below (RACC = Reference Amounts Customarily Consumed; ARF = Appropriate Reference Food). Additional information on nutrient content claims may be found in Appendix A and B of the [FDA Food Labeling Guide](#).

Nutrient	“Free”	“Low”	“Reduced/Less”
Calories	<5 calories per RACC	≤40 calories per RACC	At least 25% fewer calories per RACC than an ARF
Total Fat	<0.5g per RACC	≤3g per RACC	At least 25% less fat per RACC than an ARF
Saturated Fat	<0.5g saturated fat and <0.5g trans-fat per RACC	≤1g per RACC and ≤15% of calories from saturated fat	At least 25% less saturated fat than an ARF

Cholesterol	2mg per RACC	≤20mg per RACC	At least 25% less cholesterol than an ARF
Sodium	<5mg per RACC	Low: ≤140mg per RACC Very Low: ≤35mg per RACC	At least 25% less sodium than an ARF
Sugar	<0.5g sugars per RACC	Not Defined – Cannot be Used	At least 25% less sugar per RACC than an ARF
Other Terms Used	“zero”, “without”	“little”, “contains a small amount of”	“lower/fewer”, “modified”

3. Structure/Function Claims

- Structure/function claims require a Nutrition Facts panel on the product label.
- A “structure/function claim” can:
 - Describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans
 - “Calcium helps build strong bones”
 - Characterize the action by which a nutrient or dietary ingredient maintains such structure or function
 - “Fiber helps maintain digestive regularity”
 - Describe a benefit related to a nutrient deficiency disease, if the statement also tells how widespread the disease is in the United States.
 - Vitamin D Deficiency is associated with weakened bone health, leading to conditions such as osteoporosis. In the United States, osteoporosis affects over 10 million adults, making adequate vitamin D intake crucial for maintaining strong bones and preventing fractures.”
- These claims focus on effects derived from nutritive value. The effects must be derived from taste, aroma, or the nutritive value of the food.
- FDA does not require conventional food manufacturers to notify FDA about their structure/function claims, and disclaimers are not required for claims on conventional foods. Additional information on structure/function claims may be found in the [FDA Small Entity Compliance Guide on Structure/Function Claims](#).

4. Non-Nutritive Claims

- Non-nutritive claims are not considered nutrient content claims and are therefore not subject to nutrient content claim requirements if any of the following apply:
 - A claim that a specific ingredient is absent from the product regarding food allergies, food intolerance, religious beliefs, or dietary practices
 - A claim about a non-nutritive substance such as “contains no preservatives” or “no artificial colors”
 - An ingredient that is perceived to add value, e.g., “made with real butter”
- Unlike nutrient content claims, non-nutritive claims may qualify for nutrition labeling exemptions.

5. Common Non-Nutritive Claims

Fresh	- The food is unprocessed, in its raw state, and has not been frozen or subject to thermal processing or other form of preservation - Can be used to describe ingredients within processed foods - For example: “Made with Fresh Tomatoes” on a Pasta Sauce label
Gluten-free	- To place this claim on your product label, the food must contain a gluten level of less than 200 ppm and meet at least one of the criteria below: - Is inherently gluten-free - Does not contain a gluten-containing grain - Is derived from a gluten-containing grain but has removed the gluten
Natural	Product must not contain added color, artificial ingredients, or synthetic substances
No Artificial Colors, Flavors, or Preservatives	- This claim must be truthful to the product and its ingredients - Manufacturers may use “no artificial colors” or “made without artificial coloring” if the product is free from certified petroleum-based colors listed in 21 CFR Part 74
Non-GMO or GMO-Free	- The product label may highlight that either certain ingredients or the entire product is non-GMO or GMO-free - Use of the Non-GMO Project Verification logo requires product certification by that organization - You may develop your own icon for this claim if you are not verified by the Non-GMO Project
Organic	- The National Organic Program is governed by the USDA. The USDA Organic Seal can be used with the following examples: 100% organic on Principal Display Panel (PDP) – composed entirely of organic ingredients “Organic” on PDP – composed of at least 95% organic content - For uncertified products: “Made with organic ingredients” on PDP – at least 70% organic content, may not use USDA organic seal - No organic claims can be made on the PDP, but may identify organic ingredients within the ingredient list or include a statement of the percentage of organic ingredients on the Information Panel

6. Disease Claims

- Disease claims are determined by naming a disease and a substance.
- A “disease” references the damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunction (e.g., hypertension). A disease does not include diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra).
- Disease claims can only be used for **drugs approved by the FDA**. They cannot be used for food or dietary supplements.
- Example: “treats all forms of cancer”

IX. Labeling Time/Temperature Control for Safety Foods

1. Definitions

- A “time/temperature control for safety food” or “TCS food” is a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. This includes an animal food that is raw or heat treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and a food that because of the interaction of its A_w and pH values is designated as product assessment required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_w for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_w VALUES	pH: 4.6 OR LESS	pH: > 4.6 - 5.6	pH: > 5.6
≤ 0.92	Non-TCS food*	non-TCS food	non-TCS food
> 0.92 - 0.95	non-TCS food	non-TCS food	PA**
> 0.95	non-TCS food	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w VALUES	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	Non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	Non-TCS food	Non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	Non-TCS food	Non-TCS food	PA	PA
> 0.92	Non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

- A non-TCS food is a food that does not require time/temperature control for safety. These types of foods meet the requirements shown in Table A or B above. Non-TCS foods are safe when held at ambient temperatures after preparation. In some cases, laboratory testing is needed to determine whether a food is TCS or non-TCS. This testing can be completed by a food processing authority, which you can find by using the [Food Processing Authorities Directory](#) or contacting the [Food Producer Technical Assistance Network](#).

2. Labeling Requirements

- Labels for TCS foods should:
 - Include a statement such as “Keep Refrigerated” or “Keep Frozen” as appropriate for that product
 - Include a “Use by” date. This date is typically seven (7) days from the date the product was made (the date the product was made counts as Day 1). Products may be reformulated and/or evaluated for longer shelf lives. This may be done in collaboration with a food processing authority
- While common examples of TCS foods are provided below, the determination of whether an ingredient or product is TCS ultimately depends on the recipe of that specific product.
 - Buttercream frosting/icing
 - Cheese
 - Cheese bread
 - Cheesecake
 - Cream cheese
 - Custard
 - Fresh salsa
 - Meringue
 - Pecan pie
 - Pumpkin pie
 - Sweet potato pie

X. Product Label Examples

One Panel Label Example – Chocolate Chip Cookies

CHOCOLATE CHIP COOKIES

Ingredients: all purpose flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, soy lecithin, vanillin, natural flavor), brown sugar (molasses), sugar, walnuts, butter (cream, salt), eggs, salt, baking soda, vanilla extract (vanilla bean extractives in water, alcohol). **Contains: wheat, soy, milk, walnuts, eggs**

Grannie's Cookies, 111 Happy Lane, Anytown, VA 22554

Net Wt. 10 oz (283 g)

One Panel Label Example – Orange Juice

Orange Juice

Contains: 100% Juice

Ingredients: filtered water, orange juice concentrate.

ABC Juice Company

111 Country Road

Anytown, VA 12345

This juice is a TCS food and is clearly labeled "KEEP REFRIGERATED"

Perishable – KEEP REFRIGERATED

Net 16 fl oz (236 mL)

Fluid products use "Net" or nothing before the Net Contents Statement

One Panel Label Example – Apple Pie (Multicomponent Product)

APPLE PIE

Ingredients: Filling: apples, sugar, lemon juice, cinnamon. **Crust:** flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), butter (cream, salt), egg, salt.

Contains: wheat, egg, milk.

Virginia Pies LLC, 123 Main Street, Anytown, VA 12345

NET WT. 36 oz (2 lb 4 oz) 1.02 kg

Products that weigh between 1 and 4 pounds must be listed in ounces followed in parenthesis by pounds with the remainder in terms of ounces or common decimal fractions, followed by the metric equivalent.

Two Panel Label Example – Serrano Sauce (Front and Back/Side Label)

Front Label

Sally's Spicy Serrano Sauce

Hot Sauce



Net Wt 16 oz (484g)

Back (or Side) Label

We love this serrano sauce because of its sweet and fruity kick, balanced with the perfect amount of acid. Enjoy!

Ingredients: vinegar, serrano peppers, tomato sauce (tomato puree (water, tomato paste), water, less than 2% of: salt, citric acid, onion powder, garlic powder, red pepper), sugar, salt.

Sally's Spicy LLC

12121 E. Main Street, Richmond, VA 23181

Find our other spicy sauces at: sallysspicy.com

Two Panel Label Example – Serrano Sauce (Top and Side Label)

Top Label

**Sally's Spicy
Serrano Sauce**

Hot Sauce



Net Wt 16 oz (484g)

Side Label

Ingredients: vinegar, serrano peppers, tomato sauce (tomato puree (water, tomato paste), water, less than 2% of: salt, citric acid, onion powder, garlic powder, red pepper), sugar, salt.

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