CENTER *for* AGRICULTURE AND FOOD SYSTEMS
LAW *for* THE SUSTAINABLE FOODSHED

Your Right to Know: Making Sense of Food Labeling

Introduction

YOUR RIGHT TO KNOW
Making Sense of Food Labeling

WHY A FOOD LABELING WEBSITE?

The purpose of this website is to provide consumers like you with information to help you navigate food labels so that you may make informed food choices about the products you buy. In fact, that is the very reason for food labeling laws: to provide consumers with information so that they may make informed choices about what they purchase and consume. Unfortunately, food labels and what they mean are not straight forward. This site explains what the most common statements on food labels mean, what information must be disclosed as opposed to what information can be voluntarily included, and finally, what information is not included on food labels.

Walk into to your kitchen, pick up any food product in your pantry, and look at the label—back and front. What comes to mind as you read through the information? Do you see any of the following statements: low-fat, all natural, GMO free, vegetarian fed, no trans fat, organic, or free-range? Do you know what these statements mean? Is there any information about the product that you wanted to know but were unable to find on the label? Do you know what information the manufacturer was required to disclose to you? Do you know what information the manufacturer included voluntarily in an attempt to convince you to purchase the product and whether those statements are accurate? If you don't know the answer to some, or even all of these questions, then you certainly are not alone.

Food labels have become increasingly cluttered with confusing statements, claims, and images which can make any consumer wonder what it all means, if anything. Understanding food labels is important because they affect our purchasing decisions. Labels are a manufacturer's single most effective way to communicate directly with the consumer at the point of purchase. The information included on them is regulated by the Food and Drug Administration (FDA) under the federal Food, Drug, and Cosmetic Act (FDCA)[1]. The purpose of the law and the provisions addressing labeling were to ensure that consumers wouldn't be misled or confused when purchasing food. However, whether they realize it or not, consumers typically make purchasing decisions at the store based on the content of the food label, and those labels have become incredibly difficult to understand. Often, what the manufacturer says on a label and what a consumer thinks the manufacturer is saying are two very different things. Certain words, phrases, and images are used by manufactures to trigger certain opinions in the consumer about the product. Unless consumers know exactly what these words, phrases, and images mean, it becomes impossible to make informed choices.

HOW TO USE THIS WEBSITE

In creating this website, we have struck a balance between making food labeling information more accessible to consumers while maintaining a level of detail that is needed for accuracy.

[1] 21 U.S.C. § 321 et. al.

Here are our suggestions for making the most of the information on this site: First, read "Food Labeling Basics" to gain a basic understanding of food labeling. Second, peruse our interactive pages, which let you scroll over the example box cover and labels to learn what specific labels mean (and don't mean) and whether they are required by law or voluntary.

- **Standard Food Label**
- **What to Look for: Environmental Concerns**
- **What to Look for: Animal Welfare Concerns**

Third, if you would like more in depth information related to labeling requirements, the footnotes provide additional information, including links to relevant statutes and regulations We are constantly improving this public resource. Please let us know what you think of "Your Right to Know: Understanding Food Labeling" by sending us an e-mail at CAFS@vermontlaw.edu. Additionally, if you have questions about your food labels, please send them to us and we will incorporate them in a Frequently Asked Questions (FAQ) section on the site.

Food Labeling Basics

What is a label?[2]

Under the law, a label is the display of written, printed, or graphic material that is either physically attached to, or accompanying a product. The label includes not just the words or phrases on the package, but also the images. The courts have also considered what constitutes a label under the FDCA and determined that the definition is broad and includes information that is not physically attached to the product, but "supplements or explains" the product.[3]

What type of food products have to be labeled?

Labeling is required for all foods, including meat, poultry, and egg products, although different agencies are responsible for regulating the labels of different products.[4] Under the law, food is broadly defined, and includes any article used for food or drink for man or other animals, chewing gum, and articles used for the components of any such article.[5]

There are different labeling requirements for different categories of food.

(1) Processed Foods (any food that is not a raw agricultural commodity or a raw agricultural commodity that "has been subject to processing, such as canning, cooking, freezing, dehydration, or milling"[6]): This is the most common, and often times the most difficult, label to navigate. As a result, these products are the main focus of this guide. These products are largely regulated by the FDA. The main requirements listed in this guide are referring to these types of foods unless otherwise specified.

(2) Raw agricultural products (any food in its raw or natural state)[7]: The labeling of these products is typically exempt from the majority of requirements listed in this guide.

(3) Meat, dairy, poultry, and eggs: This is the second most common type of food label that a consumer will have to navigate. These products are largely regulated by the USDA. Many of the requirements for the

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[2] 21 U.S.C. § 321 (k),(m) (Definition in the Food, Drug, and Cosmetic Act); 21 U.S.C. § 453 (s) (Definition in the Poultry Products Inspection Act); 21 U.S.C. § 601 (o)-(p) (Definition in the Federal Meat Inspection Act);

[3] Kordel v. United States, 335 U.S. 345 (1948).

[4] 21 U.S.C. § 343 (Food, Drug, and Cosmetic Act); 21 C.F.R. §§ 101.1-101.2; 21 U.S.C. § 607 (Federal Meat Inspection Act); 21 U.S.C. § 457 (Poultry Products Inspection Act); 9 C.F.R. §§ 317.1-317.2.

[5] 21 U.S.C. § 321 (f) ("The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.").

[6] 21 U.S.C. § 321(gg).

[7] 21 U.S.C. § 321 (r) ("The term 'raw agricultural commodity' means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.").

labeling of meat, poultry, and eggs are similar to those pertaining to processed foods; however, there are specific requirements that are unique to these products.
(4) Seafood: With regard to seafood, there is not a specific labeling law governing these products. The USDA's Country of Origin Labeling laws[8] apply to seafood so consumers would have information about where their seafood came from and whether it was farm raised or wild caught. Unfortunately, the law and regulations contain many exemptions that prohibit much of this information from reaching the consumer.

What Federal Agencies Oversee Food Labeling?
There are several agencies involved in the inspection and regulation of food, but the two main agencies are: (1) The Food and Drug Administration ("FDA"); and (2) The United States Department of Agriculture ("USDA").[9] The USDA is responsible for meat, poultry, and egg products under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.[10] The FDA is responsible for all other food products under the Food, Drug, and Cosmetic Act.

Does a label have to be approved before it can be used?
Any labeling required under the FDA's authority, which governs most food products, does not have to be pre-approved. On the other hand, labeling on most USDA regulated products requires pre-approval by the department[11]. However, the USDA does allow manufacturers to use generically approved labels without pre-approval if certain conditions are met.[12]

Voluntary vs. Mandatory Labeling: Why does it matter?
This guide indicates, for each particular statement on a food label, what information manufacturers are required to disclose and what information may be voluntarily placed on a label. This distinction is important for the consumer to understand, because it speaks both to the level of government oversight and the intentions of the food producer. A required statement is heavily regulated by the reviewing agency. These statements have strict definitions and producers must meet certain detailed criteria, including font size, placement, and predominance on the package.[13] The purpose of these requirements is to ensure uniformity among labels and to provide consumers with a certain base level of information about the nutritional content, safety, and quality of food.
On the other hand, voluntary statements often do not require the same level of detail and are governed, if at all, by agency guidance about what statements are permissible. Voluntary statements are comprised of various types of additional information about the food products that manufactures can choose to disclose. Often, a manufacturer will only reveal voluntary information to the consumer that will encourage you to purchase the product. Many times, voluntary statements are not defined by the agency, allowing for a tremendous amount of leeway for manufacturers and producers.

Know Your Way Around a Label

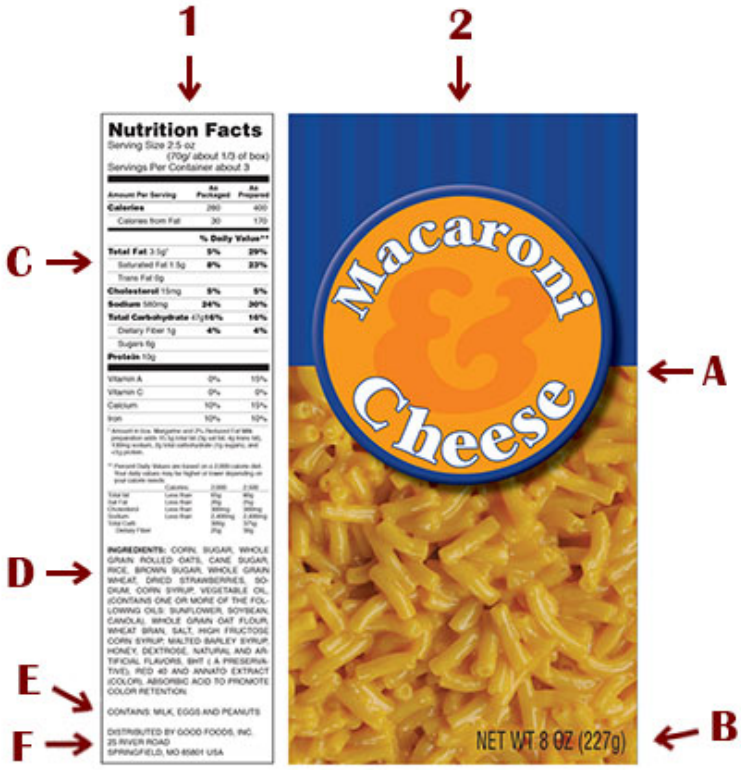
[8] 7 U.S.C. § 1621 et seq.
[9] 21 U.S.C. § 453(i)(delegating authority under the Poultry Products Inspection Act to the USDA); 21 U.S.C. § 379d(delegating authority under the Food, Drug, and Cosmetic Act to the FDA); 21 U.S.C. § 601(a)(delegating authority under the Federal Meat Inspection Act to the USDA); 21 U.S.C. § 1033(x)(delegating authority under the Egg Products Inspection Act to the USDA).
[10] 21 U.S.C. § 601(j)(defining the term meat product as "any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats."); 21 U.S.C. § 453(e)-(f); 21 U.S.C. § 1033(f)-(g)(defining the terms "egg product" and "egg.");
[11] 9 C.F.R. § 317.4(a)("No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval . . .").
[12] 9 C.F.R. § 317.5 (Under these provisions, manufacturers have to follow a very specific set of guidelines and cannot include any special claims about the product).
[13] For additional information, visit the FDA's website here: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064866.htm.

There are two key areas included on a food label: (1) the principal display panel; and (2) the information panel. (See example at right.)

(1) Principal Display Panel[14]

The principal display panel is the part of the label that is typically displayed and visible to the consumer while the product is sitting on the shelf. This is the part of the label that the consumer will first see when looking at a product, which makes it very important to the manufacturer. The following information is required to be on the principal display panel:

- A. The "statement of identity", or name of the food[15]
- B. Net quantity or amount of the product included in the package[16]



(2) Information Panel[17]

The information panel is the part of the label that is to the right of the principal display panel or included on the back of the package. The information panel is typically identified by the easily recognizable nutrition facts box, which contains caloric and nutritional information. The following information is required to be on a food label and is typically found on the information panel:

- C. Nutrition Facts[18]
- D. Ingredients[19]
- E. Name and address of manufacturer, packer or distributor[20]
- F. Allergen information[21]

Standard Food Label

This is an example of a standard food label. It includes the basic information that you will see on most all food labels. It also includes some of the basic voluntary health claims that appear frequently on most food products.

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[14] 21 C.F.R. § 101.1.
[15] 21 C.F.R. § 101.3
[16] 21 C.F.R. § 101.105 ("The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure.")
[17] 21 C.F.R § 101.2.
[18] 21 C.F.R. § 101.9; For a useful guide explaining the nutrition panel, visit the FDA's website here: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm.
[19] 21 C.F.R. § 101.4.
[20] 21 C.F.R. § 101.5
[21] 21 U.S.C. § 343(w); 21 U.S.C. §§ 374a.

(1) Statement of Identity[22]

What it is: This is simply the name of the food product. For example, "peanut butter" is a statement of identity. The statement of identity can be either: (1) the name required by law for certain products (the FDA has specific regulations for what foods must contain to be called certain things; e.g., in addition to other specific requirements, for a product to be called peanut butter, it must consist of ground peanuts to which 10% of stabilizing agents can be added, however, those stabilizing agents cannot be artificial flavorings, artificial preservatives, chemical preservatives, or color additives[23]; (2) the common or usual name of the food; or (3) an appropriately descriptive term or fanciful name.[24]

Required: Yes.[25]

Specific Requirements: The *form of the food* must be identified as part of the statement of identity if the product is available in different forms. For example, if canned sliced tomatoes are also available in diced, stewed, or chunky then the label must state "sliced tomatoes."[26]

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[22] 21 C.F.R. § 101.3; You can look up the standard of identity for specific foods on the FDA's website here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm.
[23] 21 C.F.R. § 164.150
[24] 21 C.F.R. § 101.3 (b).
[25] 21 C.F.R. § 101.3
[26] 21 C.F.R. § 101.3 (c).

Imitation food must be identified as such. A product is considered imitation if it is a substitute for and resembles another food product but is nutritionally inferior.[27] For example, imitation crab meat must be labeled as such because it is not crab, but rather processed seafood intended to resemble crab.

(2) Net Quantity[28]

What it is: This indicates the amount of food that is in the container or package. The quantity must be expressed in either: (1) weight; (2) measure; or (3) numeric count.[29] Only the amount of food in the package is included in the net quantity.[30] The weight of the package, container, wrappers, or packing material is not included in the net quantity. However, any water or other liquid added to the food is included in the net quantity.

Required: Yes. The net quantity must be placed on the bottom of the principal display panel.

Specific Requirements: If the food is a product that may lose moisture or weight during shipping, the manufacturer or producer is permitted to reasonably estimate the net weight of the product.

(3) Health Claim[31]

What it is: Any claim that expressly, or by implication, describes the relationship between: (A) the food product or any component of the food; and (B) a disease or health related condition. A claim on a label is only considered a health claim if it references disease risk reduction. These claims can either be in the form of an affirmative statement, such as "can help lower cholesterol and reduce the risk of heart disease" or they can be implied with the use of symbols or images. For example, a heart symbol placed on a package can imply that a food is heart healthy.

Required: No. This is a purely voluntary statement included by the producer or manufacturer.

Types of Health Claims:

Descriptions of general well being or dietary guidance - This type of health claim does not mention a particular disease or disease-related condition. Rather, this claim is simply a statement that links general well-being to the consumption of a certain nutrient. For example, "a multivitamin contributes to general good health." These types of claims do not require FDA pre-approval before the statement is included on the label. However, these claims must be truthful and not misleading.[32]

Pre-approved claims - There are certain health claims that the FDA has expressly authorized by regulation. These claims have been evaluated and approved by the FDA because there was significant scientific agreement, among qualified experts, that the claim was supported by the weight of the evidence.[33] A manufacturer may include any of these pre-approved claims on their label if used according to the terms of the regulation. An example of a pre-approved claim that might be seen on a food label is, "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers." The following claims have been pre-approved by the FDA: (1) calcium and vitamin D and the reduced risk of osteoporosis;[34] (2) dietary fat and the reduced risk of cancer;[35] (3) sodium and the reduced risk of hypertension;[36] (4) dietary saturated fat and cholesterol and the reduced risk of coronary

[27] 21 C.F.R. § 101.3 (e).
[28] 21 C.F.R. § 101.105
[29] 21 C.F.R. § 101.105.
[30] 21 C.F.R. § 101.105(g).
[31] 21 C.F.R. § 101.14.
[32] 21 C.F.R. § 101.93
[33] 21 C.F.R. § 101.14(c).
[34] 21 C.F.R. § 101.72
[35] 21 C.F.R. § 101.73
[36] 21 C.F.R. § 101.74

heart disease;[37] (5) fiber containing grain products, fruits, and vegetables and the reduced risk of cancer;[38] (6) fruits and vegetables and the reduced risk of cancer;[39] (7) folate and the reduced risk of birth defects;[40] (8) certain sweeteners and tooth decay;[41] (9) soluble fiber and the reduced risk of coronary heart disease;[42] (10) soy protein and the reduced risk of coronary heart disease;[43] and (11) plant sterol/stanol esters and the reduced risk of coronary heart disease.[44]

Authoritative statements claims[45] - This type of claim is one that has not been expressly authorized by a regulation. A food producer can submit a health claim to the FDA for approval if it is based on current, published, and authoritative statements from a scientific body with official responsibility for public health protection or research directly relating to human nutrition, such as the National Institute of Health, Centers for Disease Control, or the National Academy of Sciences. The FDA must act within 120 days after the health claim is submitted to prohibit the claim. If the FDA takes no action then the food producer can use the claim on its label. To date, only four health claims based on authoritative statements have been approved: (1) whole grain foods and risk of heart disease and certain cancers; (2) potassium and the risk of high blood pressure and stroke; (3) fluorinated water and reduced risk of tooth decay; and (4) saturated fat, cholesterol, and trans fat and the reduced risk of heart disease.

Qualified claims - The FDA cannot reject a requested health claim for lack of scientific evidence without first considering whether the use of a disclaimer could communicate meaningful, non-misleading information to the consumer.[46] A qualified health claim is one that requires a disclaimer. These claims still must undergo FDA approval prior to use. Even if a health claim is not supported by the weight of scientific evidence, it can still be used with an appropriate disclaimer. An example of a qualified health claim is: "Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer, however, FDA has determined that this evidence is limited and not conclusive." This disclaimer is meant to signify to the consumer that the health claim made on the label may or may not be accurate.

(4) Structure Function Claim[47]

What it is: This is a type of claim that describes the effect that an individual nutrient or substance has on the normal structure and function of the body. For example, "calcium builds strong bones" or "fiber maintains bowel regularity." The key aspect of a structure function claim is that it relates to the normal function of the human body, which is different from a health claim that deals specifically with diseases and the disease reducing or preventing qualities of a product. These types of claims do not require pre-approval from the FDA. If a producer wants to make a structure function claim they must: (1) be able to substantiate the claim; (2) notify the FDA within 30 days prior to use; and (3) must include the following disclaimer: "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."[48]

Required: No. This is a purely voluntary statement.

(5) Nutrient Level Claim[49]

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[37] 21 C.F.R. § 101.75
[38] 21 C.F.R. § 101.77
[39] 21 C.F.R. § 101.78
[40] 21 C.F.R. § 101.79
[41] 21 C.F.R. § 101.80
[42] 21 C.F.R. § 101.81
[43] 21 C.F.R. § 101.82
[44] 21 C.F.R. § 101.83
[45] 21 U.S.C. § 343(r)(2)(G).
[46] Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).
[47] 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93.
[48] 21 U.S.C. § 343(r)(6)(c).
[49] 21 C.F.C. § 101.13

What it is: This is a claim that characterizes the level of an individual nutrient in the food product.[50] For example, low fat, high in fiber, or reduced sodium. Only the following claims can be made with regard to any individual nutrient: (1) free; (2) low; (3) reduced; (4) fewer; (5) lean; (6) high; (7) less; (8) more; (9) extra lean; (10) good source; (11) light; and (12) healthy. There are specific criteria laid out in the regulations that govern when these terms can be used. For example, a label can say "fat free" if the products contains less than 0.5 grams of fat per serving.

Required: No. This is a purely voluntary statement.

What each claim means: The FDA has written regulations with specific guidelines that address when these specific claims can be used. To see a chart that includes the definitions of these different terms, visit the FDA's website here: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064911.htm.

(6) Ingredient List[51]

What it is: This is a list of the ingredients that make up the product. The ingredients must be listed individually, by their common name, and in descending order of predominance by weight. This means that the ingredients listed first weigh more than those listed later. While this sounds simple enough, it means a manufacturer can use enough of an ingredient so that it makes up the majority of the food product, but choose to use different variations of that ingredient to avoid listing it as the primary ingredient. For example, a manufacturer might use a combination of corn syrup, cane juice, fructose, glucose, etc. to make their product sweet, but avoid listing sugar as the main ingredient. The following items do not have to be included on the ingredient list:[52] (1) processing aids;[53] (2) incidental additives that are present in foods at insignificant levels and do not have any technical or functional effect in the food; and (3) substances that migrate into the food from equipment or packaging.[54]

Required: Yes. The ingredient list is typically found on the information panel of the product; however, it can also be placed on the principal display panel. It must be immediately below the nutrition facts box.

Specific Requirements:
Chemical preservatives that are added to foods must be disclosed on the food label. A chemical preservative is any chemical added to food to prevent spoilage. These substances must be listed by their common name, but the label must also specify the function of the preservative. For example, a manufacturer must state that the addition of ascorbic acid is meant to promote color retention.[55] However, this requirement does not include any substance added to food by direct exposure, for example, chemical pesticides applied to food.[56]

Spice, natural flavors, or artificial flavors can be listed individually by their common name or simply with the declaration "spices," "flavor," "natural flavor[57]," or "artificial flavor."[58]

Major food allergens must be identified either: (1) in the ingredient list; or (2) below the ingredient list following the word "Contains." The more common practice is to have a separate line listing the allergens,

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[50] 21 C.F.R. § 101.13(a).
[51] 21 C.F.R. § 101.4.
[52] 21 C.F.R. § 101.100 (a)(3) (Title of this section is Food: exemptions from labeling).
[53] Processing aids are those substances added to foods which are not present in any significant amount in the finished food product and do not affect appearance or taste. One example of a processing aid is a fruit or vegetable wash used to increase the safety of the product.
[54] An example of this is bisphenol A or BPA, which is found in many different types of packaging and has the ability to migrate into food in small quantities.
[55] 21 C.F.R. § 101.22(j).
[56] 21 C.F.R. § 101.22(a)(5).
[57] Natural flavors must be derived from either plant or animal matter. 21 C.F.R. § 101.22(a)(3). Artificial flavors are those that do not fall within that category, i.e., they are any other flavors not derived from plant or animal matter. 21 C.F.R. § 101.22(a)(1).
[58] 21 C.F.R. § 101.22(h)(1).

for example “Contains: Wheat, Milk, Egg, and Soy.” The major food allergens are milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans.[59]

(7) Nutrient Facts

What it is: This where the basic nutritional information about the product must be contained. This nutritional information must include: (1) serving size; (2) number of servings per container; (3) calories per serving; (4) calories from fat per serving; (5) total grams of fat per serving; (6) total grams of saturated fat per serving; (7) total grams of trans fat per serving; (8) total milligrams of cholesterol per serving; (9) total milligrams of sodium per serving; (10) total grams of carbohydrates per serving; (11) total grams of dietary fiber per serving; (12) total grams of sugar per serving; (13) total grams of protein per serving; and (14) a percent of daily value of vitamins and minerals per serving. Most of these must also be declared as a percent daily value on the label.[60]

Required: Yes. Typically the nutrition facts box is on the information panel; however, it can also be on the principal display panel.[61] The information must be presented in the standard form illustrated by the above image.[62]

Specific Requirements: There are several *exemptions* to this requirement, some of which include:

(1) Food that provides no significant nutrition, for example, manufacturers of coffee and many spices do not have to provide nutritional information.[63]
(2) Food offered for sale directly to consumers by a retailer whose annual gross sales is less than $500,000. This is commonly known as the small business exception.[64]
(3) Dietary supplements.[65]
(4) Raw fruits, vegetables, and fish.[66]
(5) Food that has very small packaging.[67]

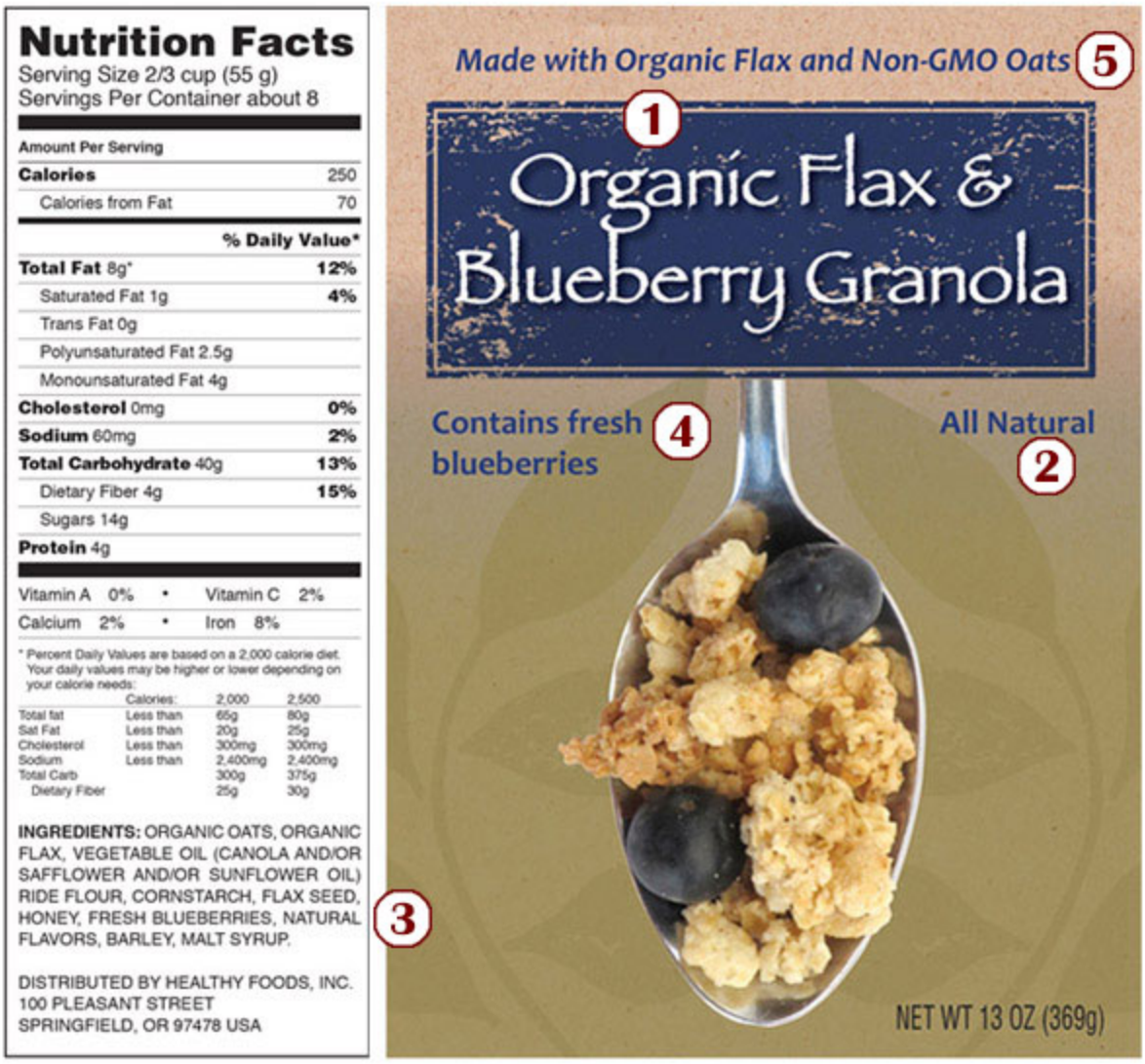
(8) Manufacturer, Packer, or Distributor

What it is: This is the name, street address, city or town, state, and zip code of the party responsible for the product.[68] The country of origin will also be located near this information. This is the company to contact with any questions or concerns about the product.

Required: Yes.

What to Look for on a Food Label: Environmental Concerns

[59] The Food Allergen Labeling and Consumer Protection Act of 2004 (“FALCPA”)(or Title II of Public Law 108-282).
[60] For some added ingredients, like salt and sugar, the FDA has not yet developed daily reference values. These substances are permitted to be added to foods in unlimited quantities, as the agency has determined they are “generally recognized as safe” based on their history of use in foods; 21 C.F.R. § 101.9.
[61] 21 C.F.R. § 101.2(b),(e); 21 C.F.R. § 101.9(i).
[62] 21 C.F.R. § 101.9(d)(1)(i).
[63] 21 C.F.R. § 101.9(j)(4).
[64] 21 C.F.R. § 101.9(j)(1).
[65] 21 C.F.R. § 101.9(j)(6)
[66] 21 C.F.R. § 101.9(j)(10).
[67] 21 C.F.R. § 101.9(j)(13).
[68] 21 C.F.R. § 101.5



(1) Organic:

What it is: This term means that a product has been produced according to the standards in the Organics Foods Production Act (OFPA).[69] Generally, a producer will not be able to use this term unless they or their supplier are certified as organic by the USDA under the National Organics Program. The exception to this general rule is that small organic farmers who sell less than $5,000 per year may use the term without being certified, but must still comply with the requirements of the OFPA.[70]

Required: No.

OFPA Standards/Requirements: If a product is labeled as organic then it has been produced under the following standards. (This is a simplified version of the OFPA requirements, for more detailed information please refer to the Guide for Organic Crop Producers.)

(1) *Organic System Plan*—An organic producer must develop an organic production or handling system plan that includes: (a) a description of practices and procedures; (b) a list of each substance used in production; (c) a description of monitoring practices and procedures; (d) a description of recordkeeping practices; (e) a description of management practices and physical barriers established to prevent

[69] 7 C.F.R. § 205.2.
[70] 7 C.F.R. § 205.101.

commingling or organic and non-organic products; and (f) additional information as necessary to insure compliance.[71]

(2) *Land Use Requirements*—There are several requirements regarding how farmers can manage their land, soil, and crop nutrients. Those include:[72]

A. Management of crop nutrients and soil fertility through cover crops, crop rotations, and the application of plant and animal materials.

B. Application of a crop nutrient or soil amendment that is included in the National List of synthetic substances. However, a farmer *cannot* use any fertilizer that contains a synthetic substance not on the National List.

C. Use of crop rotation to maintain and improve soil organic matter content, provide for pest management, manage deficient or excess plant nutrients, and provide erosion control.[73]

(3) *Seeds*—The farmer must use organically grown seeds and cannot use genetically engineered seeds or crops. There are a few exceptions to this requirement.[74]

A. Non-organically produced untreated seeds may be used if an equivalent organically produced variety is not commercially available.

B. Non-organically produced seeds treated with a substance on the National List of synthetic substances may be used if an equivalent organically produced variety is not commercially available.

C. A perennial crop grown from non-organic seeds may be sold as organic if maintained under an organic management system for at least one year.

(4) Pest Control—Farmers are required to use management practices to prevent crop pests, weeds, and disease. However, the methods that can be used are limited to:[75]

A. Crop rotation

B. Selecting plant species and varieties based on their suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

C. Introduction of predators or parasites

D. Developing habitat for natural enemies of pests

E. Use of non-synthetic lures, traps, and repellents

F. Mulching with fully biodegradable materials

G. Mowing

H. Livestock grazing

I. Hand weeding

J. Using flames, heat, or other electrical means

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[71] 7 C.F.R. § 205.201.
[72] 7 C.F.R. § 205.203.
[73] 7 C.F.R. § 205.205.
[74] 7 C.F.R. § 205.204.
[75] 7 C.F.R. § 205.206.

K. Plastic or other synthetic mulches

Specific Requirements:[76] There are four different terms that can be used on a food label to designate compliance with the National Organic Standards: (1) 100% Organic, (2) Organic, (3) Made with Organic _____, and (4) Made with specific organic ingredients. Each of these terms signifies different things, as explained below. However, if the "100% Organic," "Organic," or "Made with Organic _____" label is on a food product then the following production methods were **not** used in the production of the product or any of its ingredients, even the non-organic certified ingredients:

A. Processing aids not approved on the National List.

B. Sulfites, nitrates, or nitrites added during the production or handling process.

C. Use of non-organic ingredients when organic ingredients were available.

D. Inclusion of organic and non-organic forms of the same ingredient.

E. Produced using sewage sludge, ionizing radiation, or other excluded methods.

"100% Organic"—This label can only be used with raw or processed agriculturale products. This label means that the product contains 100% certified organic ingredients, excluding water and salt. If a product is labeled "100% Organic" it will likely also be labeled with the USDA Organic seal. Most raw or value-added agriculture products that have no added ingredients, for example, rolled oats or flour, can be designated with this label. If this label is on a processed product, it means that all ingredients and processing aids are certified organic.

"Organic"—This label can be used with raw agricultural or processed agricultural products. This label means that the product contains at least 95% certified organic ingredients, excluding water and salt. The remaining 5% of the ingredients must be either (1) organically produced or (2) if not commercially available in organic form, non-organic products produced consisted with the National List (Section 205.605 and 205.606). If a product is labeled "Organic" it can also be labeled with the USDA Organic seal. A product can still be labeled organic if it contains pesticide residues at or below five percent of the EPA's set tolerances so long as the farmer has not directly applied the pesticides and they are present as the result of drift from a neighboring farm.[77]

"Made with Organic _____"—This label is used with processed or multi-ingredient products. This label means that the product contains at least 70% certified organic ingredients, excluding water and salt. The remaining ingredients are not required to be certified organic but they cannot be produced using the prohibited methods listed above. The USDA Organic seal will not be present on these products.

Specific Organic Ingredients—This label is used with processed or multi-ingredient products. This label means that the product contains less than 70% certified organic ingredients, excluding water and salt. Only the specified ingredient must be certified organic. Unlike the "Made with Organic _____" label, the non-organic ingredients do not need to be produced and handled in any particular way. The USDA Organic seal will not be present on these products.

(2) All Natural

[76] 7 C.F.R. § 205.301.

[77] Currently, the USDA is considering applying a similar standard for the presence of genetically engineered products.

What it is: The FDA has affirmatively declined to define this term.[78] As a result, the FDA does not restrict producers from using this term in a variety of ways to mean essentially whatever suits the manufacturer's needs. However, the FDA does consider the use of "natural" as misleading and un-truthful when the product contains artificial or synthetic additives, such as colors and flavors. For example, products that contain high-fructose corn syrup, ascorbic acid, and added citric acid should not be labeled as all natural. However, because food labels subject to FDA jurisdiction do not require pre-approval,. As a result, producers can, and often do, use this term freely even though their products contain artificial colors and chemical preservatives. FDA would then need to take an enforcement action against the manufacturer to cause them to remove the misleading language.

Meat and poultry products under USDA jurisdiction may also use the term "natural." Unlike the FDA, the USDA requires pre-market approvals of all labels. As a result, the producer must demonstrate that: (1) the product does not contain any artificial flavoring, coloring ingredients, chemical preservatives, or any other artificial or synthetic ingredient; and (2) the product and its ingredients have only been minimally processed. The USDA also requires that the producer explain, on the label, what the term "natural" means.

Required: No. This statement is purely voluntary.

(3) Natural Flavor[79]

What it is: This means that the component of the product whose significant function is flavoring, as opposed to nutritional, is derived from one of the following sources: (1) a spice; (2) fruit or fruit juice; (3) vegetable or vegetable juice; (4) edible yeast; (5) herb, bark, bud, root, leaf or similar plant material; (6) meat; (7) seafood; (8) poultry; (9) eggs; or (10) dairy products. The significant function in the food must be for flavoring, and not nutritional purposes.

Required: No. Importantly, the manufacturer is not required to disclose the source of the natural flavor. If it falls into one of the categories listed above, the manufacturer can simply list "natural flavors" in the ingredients list.

(4) Fresh[80]

What it is: This terms means that the food is unprocessed, in its raw state, and has not been subject to any thermal processing or any other form of preservation. A product can still be labeled as fresh if coated in approved waxes, sprayed post-harvest with approved pesticides, rinsed in a mild chlorine or mild acid wash, or treated with ionizing radiation.

Required: No.

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[78] 58 Fed. Reg. 2301, 2407 (Jan. 6, 1993)("FDA is not undertaking rulemaking to establish a definition for 'natural' at this time. The agency will maintain its current policy not to restrict the use of the term 'natural' except for added color, synthetic substances, and flavors as provided in § 101.22. Additionally, the agency will maintain its policy regarding the use of 'natural,' as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlines in § 101.22.").

[79] 21 C.F.R. § 101.22(a)(3).

[80] 21 C.F.R. § 101.95

(5) Non-GMO / GMO Free / Non-GE / GE Free

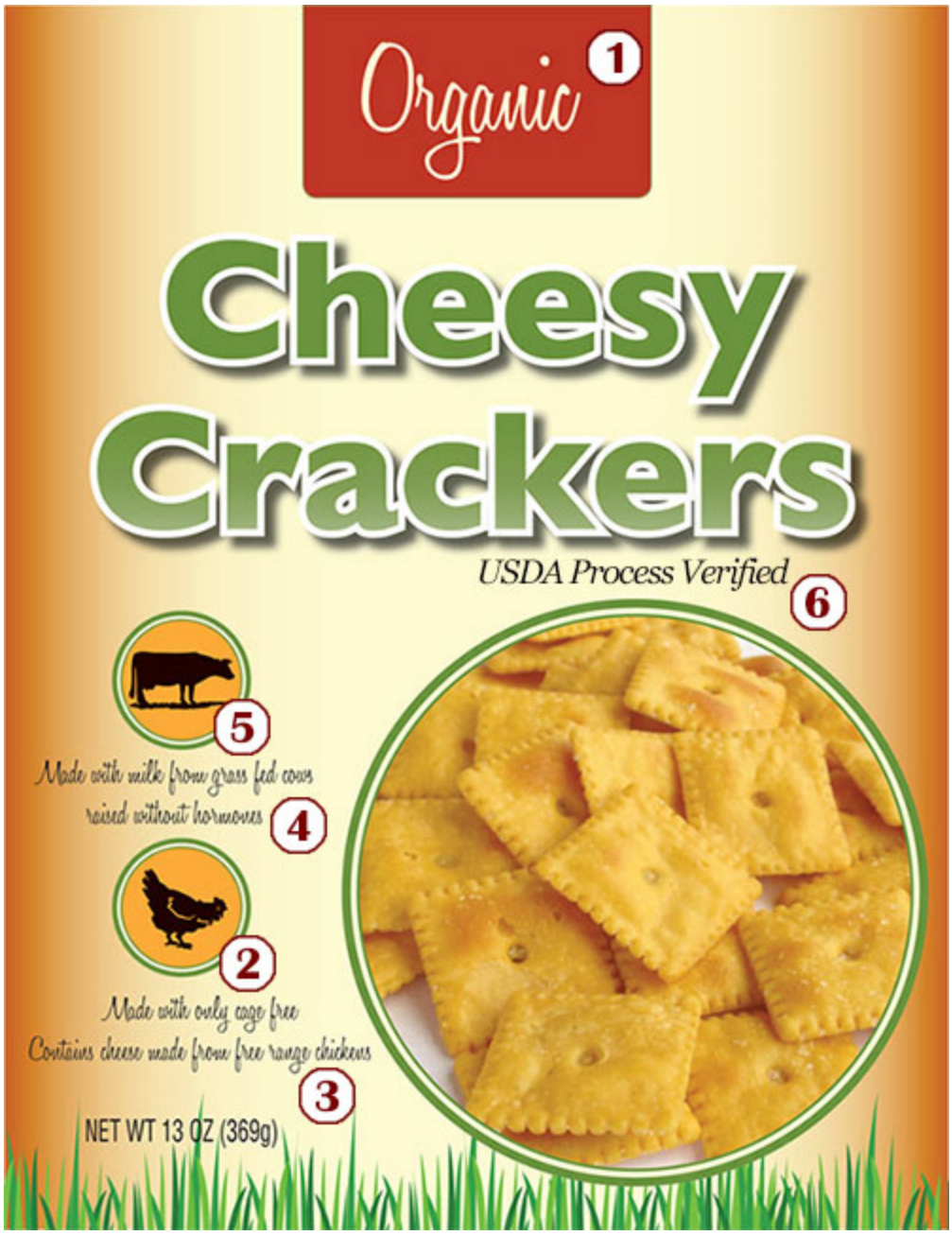
What it is: This is not been defined by the FDA. In fact, the FDA has recently issued guidance stating that they consider these terms to be misleading on most foods.[81] Food producers use these terms to communicate to consumers that certain products do not contain genetically engineered crops. Any producer can use these terms without pre-approval by the FDA.

The FDA considers misleading any label that implies that food without genetically engineered ingredients is in any way superior to those products without a similar label. However, a product can still be labeled in this manner if it contains 5% or less of genetically engineered material present in the product as the result of drift or crop contamination.

Required: No.

What to Look for on a Label: Animal Welfare Concerns

[81] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm



(1) Organic

What it is: This term means that a product has been produced according to the standards in the Organic Foods Production Act (OFPA).[82] Generally, a producer will not be able to use this term unless they or their supplier are certified as organic by the USDA under the National Organics Program. The exception to this general rule is that small organic farmers who sell less than $5,000 per year may use the term without being certified, but must still comply with the substantive requirements of the OFPA.[83]

Required: No.

[82] 7 C.F.R. § 205.2.
[83] 7 C.F.R. § 205.101.

OFPA Standards/Requirements: If a product is labeled as organic then it has been produced under the following standards. (This is a simplified version of the OFPA requirements, for more detailed information please refer to the Guide for Organic Livestock Producers.)

(1) *Origin of Livestock*—Products sold as organic are from livestock maintained under continuous organic management from the last third of gestation or hatching with 3 exceptions:[84]

- 1. Poultry must be maintained under continuous organic management from the second day of life.
- 2. Dairy animals must be maintained under continuous organic management from the first year of life.
- 3. Non-organic livestock used for breeding can be brought onto an organic operation at any time.

(2) *Livestock Feed*—Organic livestock must be provided a total feed ration composed of pasture, forage, or other feed organically produced. The following is prohibited:[85]

- A. Animal drugs and growth hormones.
- B. Supplements or additives above the amount needed for adequate nutrition and health maintenance.
- C. Plastic pellets.
- D. Formulas containing urea or manure.
- E. Feed or forage with antibiotics.
- F. Denying a ruminant the ability to actively graze in a pasture during grazing season.

(3) *Grazing and Access to Pasture*—The continuous confinement of ruminants is prohibited. Ruminants must get on average at least 30% of their feed from grazing. These animals must be grazed throughout the entire grazing period which cannot be less than 120 days per calendar year. Breeding bulls are exempt from this requirement.[86]

(4) *Livestock Health Care Practices*—Farmers are required to establish and use preventive livestock health care practices, including:[87]

- A. Selection of species based on site specific conditions.
- B. Provide feed sufficient to meet nutritional requirements.
- C. Provide appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of disease and parasites.
- D. Provide conditions that allow for exercise, freedom of movement, and reduction of stress appropriate to the species.
- E. Perform physical alterations as needed to promote animal welfare and in a manner that minimizes pain and stress.
- F. Administer vaccines.

Farmers are **prohibited** from:

- A. Treating livestock with antibiotics.
- B. Administering drugs or other vaccines in the absence of illness.
- C. Administering growth hormones and synthetic parasiticides on a routine basis or prior to slaughter.
- D. Withholding medical treatment from a sick animal

(5) *Livestock Living Conditions*—Farmers are required to establish and maintain year-round living conditions that accommodate the health and natural behavior of animals, including:[88]

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[84] 7 C.F.R. § 205.236.
[85] 7 C.F.R. § 205.237.
[86] 7 C.F.R. § 205.237.
[87] 7 C.F.R. § 205.238.

- A. Year-round access to outdoors, shade, shelter, exercise areas, fresh air, clean water, and direct sunlight.
- B. Appropriate clean, dry bedding.
- C. Shelter designed to allow for natural maintenance, comforting behaviors, the opportunity to exercise, and reduction of injury.

However, farmers are allowed to temporarily confine livestock:

- A. If there is inclement weather.
- B. During a certain stage of an animal's life, except that lactation is not a stage of life.
- C. When conditions could jeopardize the health, safety, or well-being of the animal.
- D. If there is risk to the soil or water.
- E. During the sorting or shipping of animals.
- F. For preventative healthcare procedures.
- G. For breeding.
- B. To administer drugs or other vaccines in the absence of illness.

(2) Cage Free[89]

What it is: This term is not defined by the USDA. However, if a USDA-inspected egg producer wants to use the term "cage free" on its egg cartons, the agency must first verify the claim. The USDA will allow the use of the term if the poultry flock was able to freely roam a building, room, or enclosed area with unlimited access to food and fresh water.

Required: No.

(3) Free Range or Free Roaming[90]

What it is: This term is not defined by the USDA. However, if a USDA-inspected producer wants to use the term "free range," the agency must first verify the claim. The USDA will allow the use of the term if the flock was provided shelter in a building, room, or area with unlimited access to food, fresh water, and continuous access to outdoors, which can mean the facility has a window.

Required: No.

(4) No Added Hormones / Raised without Hormones

What it is: If a USDA-inspected producer wants to use this term, the agency must first verify the claim. The USDA will allow the use of the term if the producer can document that no hormones were administered during the course of the animal's lifetime. As a general matter, hormones are only approved for use in beef cattle and lamb production. They cannot be used in poultry, hogs, veal calves or exotic, non-amenable species. As a result, the "raised without hormones" label will not be approved for these species unless it is directly followed with the following statement: "Federal regulations prohibit the use of hormones in poultry."

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[88] 7 C.F.R. § 205.239.

[89] http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateC&leftNav=NationalOrganicProgram&page=NOPConsumers&description=Consumers

[90] http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateC&leftNav=NationalOrganicProgram&page=NOPConsumers&description=Consumers

Required: No.

(5) Grass fed

What it is: If a USDA-inspected producer wants to use this term, the agency must first verify the claim. The USDA will allow the use of the term if the producer can show that the animals received a majority of their nutrients from grass throughout their life. Unlike the organic label, this label does not limit the use of antibiotics, or hormones.

Required: No.

(6) USDA Process Verified

What it is: The USDA offers this seal to producers as a marketing tool, and it functions similarly to the claim that a product is all natural. Participating producers submit their standards for consideration, and once the USDA grants approval of those standards, the department conducts audits to verify that the company is following its own standards. For example, the meaning of a term such as 'humanely raised' can vary widely among producers, yet all are eligible to receive USDA process Process Verified approval for the claim so long as each is following its own standards.

Required: No.

What's Not on the Food Labels

Genetically engineered

What it means: Genetic engineering is the process of "manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques."[91]

Why it's not included: The FDA has determined that genetically engineered food does not differ in any material way from non-genetically engineered food and thus does not need to be labeled as such.[92] The FDA's position is that genetically engineered foods must go through the same safety requirements as traditional foods and thus do not pose a safety risk.[93] Food that is labeled as certified organic cannot contain genetically engineered food.

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[91] United States Department of Agriculture, *Glossary of Agricultural Biotechnology Terms*, available at http://www.usda.gov/wps/portal/usda/usdahome?contentid=BiotechnologyGlosary.xml&navid=AGRICULTURE. The term "genetic engineering" is often used synonymously with the term "genetic modification" even though the two terms are not identical. "Genetic modification" is defined as "[t]he production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods. Some countries other than the United States use this term to refer specifically to genetic engineering." *Id.* The term genetic modification includes "more traditional methods" such as hybridization or cross breeding, which do not involve the insertion of foreign genetic material whereas the term genetic engineering does not.

[92] Food and Drug Administration, Guidance Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance, available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.

[93] http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm346030.htm

Crops that are genetically engineered: Corn, soybean, canola, cotton, alfalfa, cantaloupe, flax, papaya, plum, potato, radicchio, squash, sugar beets, tomato, and wheat. Genetically engineered corn is present in most highly processed foods.

Third Party Certifications

There are now a lot of certifications that are provided to manufactures from third parties. These third party certifications are not defined or regulated by the federal government, but can assist producers and manufacturers in complying with federal laws and regulations.

http://www.carbonfund.org/offset/product-certification

http://www.certifiedhumane.org/

http://www.demeter-usa.org/for-farmers/farm-processing-standards.asp

http://fairtradeusa.org/certification

http://www.rainforest-alliance.org/agriculture/certification

http://www.animalwelfareapproved.org/

http://www.nongmoproject.org/learn-more/understanding-our-seal/

http://www.c2ccertified.org/

http://foodalliance.org/standards