

## How and Why to Read Food Labels

The Federal Food, Drug and Cosmetic Act ([FFDCA](#)) provides labeling guidelines for all “foods,” a technical term which it defines as<sup>1</sup>:

1. articles used for food or drink for man or other animals
2. articles used for components of any such article
3. flavorings, colorings, additives and spices
4. dietary supplements
5. chewing gum

The code was amended in 2004 by the Food Allergen Labeling Consumer Protection Act ([FALCPA](#)). This required manufacturers to use a “plain language” label to disclose the presence of any of the top eight food allergens responsible for 90% of all reactions. These are dairy, egg, wheat, soy, fish, shell fish, tree nuts and peanuts (on gluten labeling, see section below). Manufacturers are also required to disclose *the source* of their ingredients when they contain protein from any of these eight foods and to do so by using these eight “plain language” terms. Thus, ghee must be disclosed as “milk”, because the only way to make it is to clarify butter, and so it contains milk protein. Calcium lactate, however, can be derived from milk or from a vegetable source, so if the source is milk is must be labeled as “milk”, but if from beets, no disclosure is necessary. This can lead to consumer confusion over whether a product is safe or mislabeled. In all cases, [FALCPA](#) is concerned only with the source.

Labels are required to conform to one of two formats:

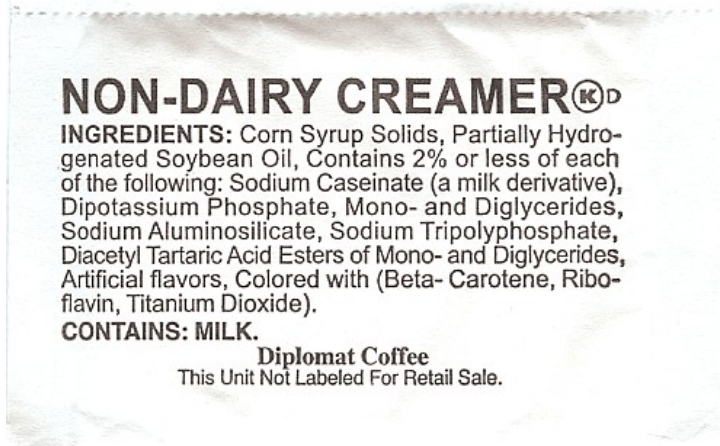
**Option #1:** Labels must list ingredients using a) plain language terms for the eight allergens or b) use technical terms but also include plain language terms in parentheses. Adding a “contains” statement as the label below does is optional using this method.

**INGREDIENTS:** ENRICHED EGG NOODLES (ENRICHED WHEAT FLOUR [WHEAT FLOUR, NIACIN, FERROUS SULFATE {IRON}, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID], WATER, WHOLE EGG SOLIDS), SALT, MONOSODIUM GLUTAMATE, SUGAR, CORN MALTODEXTRIN, WHEAT STARCH, POWDERED CHICKEN MEAT, HYDROLYZED CORN PROTEIN, MODIFIED CORN STARCH, DEHYDRATED ONION, DEHYDRATED PARSLEY FLAKES, SILICON DIOXIDE, SPICE, AUTOLYZED YEAST, CHICKEN FAT, PROPYLENE GLYCOL, NATURAL FLAVORS (CONTAINS CELERY EXTRACTS), TURMERIC, POLYSORBATE 80, DISODIUM INOSINATE AND DISODIUM GUANYLATE, SOYBEAN OIL; BHA, PROPYL GALLATE AND CITRIC ACID AS PRESERVATIVES.  
**CAPSULE CONTAINS:** CHICKEN FAT, PARTIALLY HYDROGENATED SOYBEAN OIL, GELATIN, MONOGLYCERIDES; BHA, PROPYL GALLATE AND CITRIC ACID AS PRESERVATIVES.  
**CONTAINS WHEAT, EGG, SOYBEANS**  
**PROCESSED ON EQUIPMENT THAT ALSO PROCESSES WHEAT, SOYBEANS, MILK, EGG.**

**Option #2:** Immediately following or to the side of the list of ingredients, the word “contains” must appear “followed by the name of the food source from which the major food allergen is derived”

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<sup>1</sup> [21 USC 321 \(f\); 21 USC 321 \(ff\)\(3\)\(b\)\(ii\).](#)



***note: Be careful of marketing terms. The present state of the law permits a product to be labeled “non-dairy” even though the ingredient label states that it contains milk.***

In the case of tree nuts, the kind of nut must be disclosed (e.g. walnut, pecan, etc.) and in the case of fish or crustacean shellfish, the species must be disclosed (e.g. flounder, lobster, etc.).

### Exceptions

[FALCPA](#) permits three exceptions to the labeling law:

1. Very highly refined oils need not declare the source of the oil on labels
2. Evidence may be supplied in support of an exemption from the labeling law, and it may be approved, if in FDA’s judgment, the petitioner has proven by means of scientific evidence “that such food ingredient, as derived by the method specified in the petition, does not cause an allergenic response that poses a risk to human health.”
3. A manufacturer may provide the FDA scientific evidence that proves that a) an ingredient does not contain one of the eight allergenic proteins or b) the FDA determine that the ingredient does not pose an allergic response that threatens human health.

### Penalties

- Strict Liability. If a product contains one of the eight allergens *at any scientifically detectable level*, yet does not bear a plain label notice, the manufacturer is in violation of [FALCPA](#) regardless of intention or knowledge of wrong doing, even in the case of accidental cross-contamination at the point of production or earlier in the supply chain ([21 USC 331](#)).
- Responsibility. A violation can result in the conviction of corporate officials who are deemed liable under the law, because they have power to prevent or correct violations. “All that need be shown is that individual was in position of power or authority to detect, prevent or correct violations of this section.” ([21 USC 331](#)). In practice, the FDA rarely punishes manufacturers for mislabeling.

### Grey Areas:

- Protocols. The FDA requires all food processors to employ Good Manufacturing Practices (GMPs), which proscribe methods, equipment, controls and minimum sanitary standards for processing food. GMPs reduce the likelihood of cross contamination ever occurring to a minimum once production begins, but testing the final product for purity is not required before it is released to market. Hazardous Analysis and Critical Control Points (HACCP)

are optional and afford a higher level of protection by identifying points of potential contamination throughout the entire supply and production line and by implementing quality checkpoints along the way. There are, however, several reasons why a manufacturer may not be able to affirm with 100% certainty, despite claims to the contrary, that 100% of its products are 100% allergen free before leaving the factory:

- Raw materials often change hands many times before production and can be sourced from multiple vendors.
- A brand may be packaged and processed in different facilities with other brands or made by third parties under contract. This can be particularly tricky when an allergen like peanut or wheat flour is prone to going airborne
- The different protein tests have varying degrees of accuracy and testing down to 1 PPM is generally impossible.
- Not all products can be tested for all proteins and taking samples holds open the possibility of contamination occurring at a later stage in production.
- People can develop allergies to virtually anything.

Currently, the FDA does not stipulate acceptable limits in parts per million (PPM) for any of the eight allergens, nor does it set PPM thresholds above which an allergen must be declared on the label. The FDA merely makes manufacturers shoulder the risk of anyone having a reaction by holding them strictly liable.

- Additional Quality Controls. Many allergy-friendly manufacturers produce allergen/cross-contamination statements that outline the risks of cross contamination and additional precautions taken to reduce those risks. These statements may include notice of:
  - the use of Enzyme-Linked Immuno-Sorbent Assay (ELISA) tests for particular proteins before or after production
  - the PPM of various proteins
  - Hazardous Analysis and Critical Control Points (HACCP), an optional set of protocols to prevent cross contamination that is stricter than what the FDA ordinarily requires
  - other allergens handled in the same facility or shared equipment
  - the use of dedicated free-from facilities or dedicated free-from machinery

Certainly, acknowledgment that risks exist is more forthright than silence, and opting for precautions that exceed FDA requirements is a measure of a manufacturer's concern for public health and its own reputation. If you have food allergies, look for these products. It is helpful to know, if you have a severe peanut allergy for instance, that a product with a peanut-free recipe was nevertheless produced in a facility that handles peanuts. Free From Market publishes manufacturers' Allergen Cross Contamination statements on our product pages whenever, but only if, they make these public. Unless a manufacturer is willing to assume legal risk in print, the severely allergic or intolerant ought not to trust hearsay.

- Recalls. A manufacturer's good reputation for quality is the primary safeguard for making sure that contaminated products never reach the marketplace. Consequently, most recalls are initiated by the manufacturer, and the FDA posts 4-8 recall notices per week on its website for undisclosed ingredients. If a manufacturer fails to catch a contaminated product on its own, both the manufacturer and the public will be made aware of a mislabeled product only after someone has had a reaction to it and has registered a complaint with the FDA. To receive FDA recall notices, register [here](#).

## Warnings to the Allergic Consumer:

Given nature of [FALCPA](#) and its limitations, the free from consumer ought to take additional precautions.

- Possible Ingredients. “May contain” statements are neither required nor regulated by the FDA, and although some may believe that their use somehow mitigates the provision of strict liability, they do not. Either a product contains an allergen or it does not, and ignorance is no defense for mislabeling. Alternatively, a manufacturer’s genuine concern for food allergy sufferers could be the motive for using such a statement, beware of consigning the safety of those severely allergic or intolerant to an interpretation of someone else’s intent. The [Food Allergy and Anaphylaxis Network](#) and the [Illinois Food Allergy Education Association](#) recommend that those with food allergies avoid such products.
- Recipes Change. Manufacturers have a right to change their ingredients and they often do. Do not assume that a brand is safe because you often eat it. If you have a food allergy, you must read every product label of every food every time. NO EXCEPTIONS.
- Read the Whole Label. Foods may contain allergens, even if they do not bear a “contains” statement. Such statements are required only if the manufacturer does not use plain language terms in parentheses (see option #1 above).
- When in Doubt Call the Manufacturer. If a label does not inspire confidence, call the manufacturer and ask about their recipe.
- Gluten. Gluten is a sticky protein composite found in wheat, rye, barley, crossbred hybrids like triticale (wheat/barley) and most oats. Manufacturers must disclose wheat as an allergen, but not gluten. In fact, as of January 2009, the FDA has not defined the term “gluten free,” but a regulation proposed in January 2007 could, if enacted, make 20 parts per million the maximum amount of gluten that a “gluten free” product could contain without being mislabeled. The FDA is receiving public comments on the proposal. In the meantime, if you have Celiac Disease or are gluten intolerant look for a gluten-free certification seal from the Gluten Free Certification Organization ([GFCO](#)) and read for [gluten synonyms](#).
- Synonyms. In theory [FALCPA](#) dispenses with the need to learn synonyms for food allergens, but only in so far as one blindly trusts manufacturers to label their products accurately. Lack of FDA regulation makes reading for gluten a necessity. Moreover, frequent product recalls, grey areas in the act, reliance on self-regulation, the lack of FDA mandated allergen thresholds and the vagaries of the manufacturing process all suggest that mislabeling is a common occurrence. Indeed, each week the FDA posts 4-8 recall notices due to mislabeled or cross contaminated products. One must still learn allergen synonyms. Click on the links below for printable cards bearing many — though not all — of the common synonyms for the top eight food allergens and gluten.

MILK  
EGG  
WHEAT  
SOY  
PEANUTS  
TREE NUTS  
FISH  
SHELL FISH  
GLUTEN