



Allergen Labeling Update: Final Food Allergen Labeling Guidance

On January 6, 2025, the U.S. Food and Drug Administration (FDA) released the guidance documented: *Final Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act* (Edition 5). This final guidance replaced both the draft and final guidance documents on food allergen labeling that were issued in November 2022. The guidance updates food allergen policies that will require some firms to make labeling changes and may change some allergen cross contact control practices. Both FDA and the Ohio Department of Agriculture are encouraging firms to make appropriate label changes during their next printing. A summary of updates follows:

- The list of tree nuts FDA considers as major food allergens was changed.
 - Coconut is no longer considered a major food allergen.
 - Beech nut, butternut, chestnut, chinquapin, cola/kola nut, ginko nut, hickory nut, palm nut, pili nut and shea nut are no longer considered major food allergens.
 - FDA clarified that **only** tree nuts listed in Appendix 1 from the updated guidance are considered major food allergens. Other tree nuts not listed in the table should not be included in the “Contains” statement, even if they are used as an ingredient, because the “Contains” statement is reserved for major food allergens. The updated guidance reemphasizes that the “Contains” statement must list the specific type of tree nut (e.g., almond) and cannot broadly declare “tree nuts” as the major food allergen.
 - Appendix 1 from updated guidance

Tree Nuts FDA Considers as Major Food Allergens with their Common or Usual Names and Scientific Names.

Common or usual name	Scientific name (Family name is identified in parentheses.)
Almond	<i>Prunus dulcis</i> (Mill.) D.A. Webb (Rosaceae)
Black walnut	<i>Juglans nigra</i> L. (Juglandaceae)
Brazil nut	<i>Bertholletia excelsa</i> Humb. & Bonpl. (Lecythidaceae)
California walnut	<i>Juglans californica</i> S. Watson (Juglandaceae)
Cashew	<i>Anacardium occidentale</i> L. (Anacardiaceae)
Filbert/Hazelnut	<i>Corylus</i> spp. (Betulaceae)
Heartnut/Japanese walnut	<i>Juglans ailantifolia</i> Carriere var. <i>cordiformis</i> (Makino) Rehder (Juglandaceae)
Macadamia nut/Bush nut	<i>Macadamia</i> spp. (Proteaceae)

Pecan	<i>Carya illinoensis</i> (Wangenh.) K. Koch (Juglandaceae)
Pine nut/Pinon nut	<i>Pinus spp.</i> (Pineaceae)
Pistachio	<i>Pistacia vera</i> L. (Anacardiaceae)
Walnut (English, Persian)	<i>Juglans regia</i> L. (Juglandaceae)

- Expanded interpretation of “milk” as a major food allergen to include milk from goats, sheep, and other ruminants for food allergen labeling purposes.
 - When milk from ruminant animals other than cows is used as an ingredient, it must be declared in the ingredient list by common or usual name, such as “goat milk”.
 - For food allergen labeling purposes, milk ingredients from animals other than cows, should also include the name of the animal source, such “whey (goat milk)” in the ingredient list or “Contains goat milk” in a separate “Contains” statement, or both.
- Expanded interpretation of “eggs” as a major food allergen to include eggs from ducks, quail and other fowl for food allergen labeling purposes.
 - When eggs from birds other than chicken is used as an ingredient, it must be declared in the ingredient list by common or usual name, such as “duck egg”.
 - For food allergen labeling purposes, egg ingredients from birds other than chickens, should also include the name of the bird source such as “ovalbumin (duck egg)” in the ingredient list or “Contains duck egg” in a separate “Contains” statement, or both.
- Specified that “allergen-free” claims should not be accompanied by allergen advisory statements because it would be confusing for consumers. For example, “milk-free” and “may contain milk” should not appear on the same product label and labeling.
- Specified that allergen declaration in an ingredients list or in a “Contains” statement should also not be accompanied by an allergen advisory statement for the same allergen. For example, “Contains milk” and “may contain milk” should not appear on the same product label and labeling.
- Emphasized that the species be declared for fish (e.g., bass, flounder, cod) and Crustacean shellfish (e.g., crab, lobster, shrimp) in the ingredient list or the “Contains” statement and cannot broadly declare “fish” or “Crustacean shellfish” as the major food allergen.
- Specified that for purposes of the definition of a “major food allergen,” the term “wheat” means any species in the genus *Triticum*. Thus, wheat would include grains such as common wheat (*Triticum aestivum* L.), durum wheat (*Triticum durum* Desf.), club wheat (*Triticum compactum* Host.), spelt (*Triticum spelta* L.), semolina (*Triticum durum* Desf.), Einkorn (*Triticum monococcum* L. subsp. *monococcum*), emmer (*Triticum turgidum* L. subsp. *dicoccon* (Schrank) Thell.), Khorasan (*Triticum polonicum* L.), and triticale (x *Triticosecale* ssp. Wittm.).

- Clarified that the food allergen labeling requirements of the federal Food, Drug, and Cosmetic (FD&C) Act extend to foods packaged by a retail or foodservice establishment that are offered for sale for human consumption. However, these labeling requirements do not apply to foods provided by a retail or food service establishment that are placed in a wrapper or container in response to a consumer's order, such as the paper or box used to transport a sandwich that has been prepared in response to a consumer's order.

The final guidance can be found on FDA's website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5>