

## Laying Down the Law on Labeling Food Allergens

By Justin Prochnow

Food safety continues to be one of the highest priorities of the U.S. Food and Drug Administration (FDA) and, for that reason, the proper labeling of food allergens is a specific area of focus and concern for the FDA when scrutinizing food labels. The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2006 amended the Federal Food, Drug, and Cosmetic Act at 21 U.S.C. §343(w) and requires that a food containing an ingredient that is or contains protein from a “major food allergen” must declare the presence of the allergen on the label. The FDA considers the failure to properly identify food allergens to be a major potential risk to the safety of consumers.

There are eight major food allergens identified in FALCPA that, at the time FALCPA was passed, accounted for more than 90% of all documented food allergies in the US. They include five specific allergens—milk, wheat, soybeans, peanuts and eggs—and three groups of allergens—fish, crustacean shellfish and tree nuts. Pursuant to FALCPA, the specific species of fish, crustacean shellfish or tree nut must be identified when one of those allergens is present in a food.

Identification of food allergens can be carried out in one of two manners: One way is for the food allergen to be identified in the ingredients list, either if it is evident in the common or usual name used in the ingredients list, or in parentheses after the common or usual name, such as “whey (milk).” The second option is to place the word “contains,” followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients. In this case, it must be in a type size that is

no smaller than the type-size used for the list of ingredients, i.e., “Contains: milk, eggs, peanuts.”

While some companies opt to include a cautionary warning that products are processed in a facility that also produces products containing one or more major food allergens, such cautionary warnings are not covered by FALCPA and not required by the FDA.

Food products that contain undeclared food allergens are considered misbranded (mislabelled) products and are thus in violation of the Federal Food, Drug, and Cosmetic Act. Companies are usually strongly encouraged to recall products with undeclared food allergens, and the FDA now can likely initiate mandatory recall procedures due to the potential for serious health consequences.

The failure to properly identify food allergens continues to be one of the more frequently cited violations alleged in FDA warning letters. In 2014 alone, the FDA issued and posted at least 12 warning letters that identified the failure to declare one or more major food allergens as one of the alleged labeling violations. Of course, companies also face civil action in the form of a product’s liability case or a false labeling action from consumers who are sensitive to food allergens and consume a product with undeclared food allergens.

Accordingly, the proper labeling of food allergens on food labels is critical for food, beverage and dietary supplement companies. The failure to identify food allergens could subject a company to regulatory and legal consequences that could result in huge impacts on the bottom line for the company.

*Justin Prochnow is an attorney and shareholder in the Denver office of the international law firm of Greenberg Traurig LLP. His practice concentrates on regulatory and legal issues affecting the food and beverage, dietary supplement and cosmetic industries. He can be reached at 303-572-6500 or [prochnowjj@gtlaw.com](mailto:prochnowjj@gtlaw.com) and is on Twitter at @LawguyJP. This is for informational purposes only and is not intended to be construed or used as general legal advice. The opinions expressed are those of the author exclusively.*