

FDA Now Enforcing "Gluten-Free" Labeling Rule

As of August 5, 2014, all packaged foods labeled "gluten-free" (or other equivalent terms, such as "free of gluten," "no gluten" and "without gluten") must meet the requirements of the U.S. Food and Drug Administration's (FDA) final rule setting forth the standards for gluten-free labeling. This rule was published back in August 2013 and gave food manufacturers one year to make the necessary changes in formulation and labeling of foods that voluntarily bear this claim. Restaurants and other establishments making a gluten-free claim on their menus should also be consistent with the FDA's rule.

The final rule defines "gluten-free" foods as those containing less than 20 parts per million (ppm) gluten. Foods may be labeled "gluten-free" if they are inherently gluten free, or do not contain an ingredient that is (1) a gluten-containing grain (e.g., spelt wheat); (2) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or (3) derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 ppm or more gluten in the food.

In addition, foods that include the term "wheat" in the ingredient list or a separate "contains wheat" statement on the packaging and also are labeled "gluten-free" will be deemed misbranded unless it is clear on the packaging that the food has been processed to allow it to meet the gluten-free standards set by the FDA.

The FDA's new "gluten-free" definition provides consumers with celiac disease, and others who simply have chosen to eliminate the naturally occurring protein from their diets, more confidence in their food choices. It will also help food manufacturers avoid liability for false advertising if they meet the FDA-established threshold of less than 20 ppm.

If you would like to know more about product labeling or specifically how the FDA's final rule on gluten-free labeling may affect your business, Reinhart's attorneys specializing in food and beverage law would be glad to help you.

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