

New Gluten-Free Labeling Requirements for Fermented Foods

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On November 19, 2015, the **U.S. Food and Drug Administration (FDA)** proposed new requirements for manufacturers of fermented or hydrolyzed foods to label their products “gluten free.” The [proposed requirements](#) are intended to increase certainty in gluten-free labeling for the three million people with Celiac Disease in the United States. The requirements will impact food and beverage companies that label products gluten-free that contain fermented or hydrolyzed foods such as yogurt, cheese, vinegar and FDA-regulated beer and wine.

The proposed requirements amend a rule adopted by FDA in 2013 (now codified at 21 CFR 101.91) that creates standards to voluntarily label products “gluten free.” The 2013 rule requires manufacturers who rely on analyzing their product for gluten content to be able to detect the presence of 20 parts per million gluten in their products. According to FDA, today’s proposed rule is necessary because the current testing methods for gluten content in fermented, distilled and hydrolyzed products yield uncertain results and therefore may cause inaccurate labeling of products as gluten-free.

The proposed rule requires manufacturers of fermented or hydrolyzed foods to demonstrate compliance with the gluten-free labeling requirements of 21 CFR 101.91 *before* their product is fermented or hydrolyzed. Additionally, the manufacturer must document that potential for cross-contamination of the product with gluten has been assessed and addressed for the entire manufacturing process. The rule further requires manufacturers that use fermented or hydrolyzed ingredients to demonstrate, through record keeping, that their product is compliant with the standards in 21 CFR 101.91(a)(3). The rule states that sufficient documentation may be in the form of test results or certificates of analysis. Manufacturers must retain the relevant records for two years after the product is introduced into interstate commerce.

Comments on this proposed rule may be submitted [here](#) until February 16, 2016.

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