

FDA EXTENDS PUBLIC COMMENT PERIOD FOR NEW REGULATION ON LABELING “GLUTEN-FREE” FOODS AND BEVERAGES

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The US Food and Drug Administration (FDA) recently announced that it has extend the period for public comments on a proposed rule to establish requirements for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients, and bear a “gluten-free” claim. FDA is extending the comment period for the proposed rule on gluten-free labeling for fermented or hydrolyzed foods by 60 days.

The agency originally introduced the [Proposed Rule for Gluten-Free Labeling of Fermented or Hydrolyzed Foods](#) on November 18, 2015. Before the recent 60 day extension, the public comment period would have ended on February 16, 2016. The new closure date for public comments will be 60 days from the date that a notice reopening the comment period appears in the Federal Register. The new rule’s Federal Register Docket Number is [FDA-2014-N-1021](#), and the relevant Federal Register Docket Name is: “*Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.*”

The proposed rule is relevant to food and beverage suppliers because manufacturers continue to introduce gluten-free products, responding to a market demand that appears to extend beyond the population of consumers with celiac disease or gluten intolerance.¹ In the year leading up to April 2015, ten percent (10%) of all global food product launches involved a gluten-free product. In the United States, 18% of new food launches involved a product labeled as “gluten-free.”

The proposed rule does not require “gluten-free” labeling but rather establishes compliance methods for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients that bear a voluntary “gluten-free” labeling claim.

A “fermented food” is defined by the FDA as “one that has undergone fermentation—a process that typically involves the conversion of complex organic compounds, especially sugars and other carbohydrates, to simpler compounds such as lactic acid and ethyl alcohol.” Fermentation has long been used to preserve or produce foods with characteristic flavors or textures. During fermentation, proteins such as gluten break apart into smaller groups of amino acids known as peptides. The FDA rule cites examples of fermented foods as including cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine.

¹ According to the FDA, celiac disease is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain proteins referred to as gluten occurring in wheat, rye, barley, and crossbreeds of these grains. The main protein of wheat gluten is gliadin; the similar proteins of rye and barley are termed secalin and hordein, respectively. Both of the major protein fractions of gluten, gliadins and glutenins, are active in celiac disease. All the gliadins and glutenins subunits are reported to be harmful for individuals with celiac disease. Celiac disease has no cure, and FDA advises individuals who have this disease to avoid all sources of gluten in their diet to protect against adverse health effects associated with the disease.

A “hydrolyzed food” is defined by the FDA as “one in which a food's chemical components—such as proteins—are broken into smaller organic compounds by reaction with water.” These reactions are often accelerated by enzymes. One common application of hydrolysis in food manufacturing is the hydrolysis of plant proteins—such as soy protein. Hydrolyzed soy proteins are often used as an ingredient to increase digestibility of the protein, to enhance flavor, or to improve texture in processed foods such as soups, sauces, and seasonings. The FDA rule cites examples of foods using hydrolyzed plant proteins as flavor enhancers that include soups, chili, sauces, gravies, stews, dips, and some snacks like potato chips and pretzels.

Because the food industry is labeling so many of these products as “gluten-free,” FDA has concluded that specific labeling definitions are needed. Although FDA issued an initial gluten-free labeling rule in 2013, the agency intends for the currently proposed rule to clarify requirements for food categories that involve different forms of processing and gluten/protein detection. The new rule, if adopted in its current form, would address gluten-free labeling for products such as yogurt, sauerkraut, pickles, cheese, green olives, vinegar, and FDA-regulated beers. The new rule also includes distilled products not intended for consumption as beverages.

Most alcohol beverages are regulated by the US Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB’s current policy on “gluten-free” label claims on alcohol beverage labels can be found in [TTB Ruling 2014-2](#). TTB has indicated that it may revise its own gluten claim policy once FDA has issued a final rule or other guidance.

For more information regarding the FDA’s regulation on “gluten-free” product labeling, or for assistance in commenting on the agency’s proposed rule, please contact GrayRobinson’s [Food Law Group](#) at foodlaw@gray-robinson.com or (866) 382-5132.