FDA Publishes Final Rule on Gluten-Free Labeling of Fermented or Hydrolyzed Foods

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Key Points

- A new FDA rule clarifies when food manufacturers may label fermented or hydrolyzed foods as gluten-free.
- Manufacturers making gluten-free claims must maintain records showing that the foods or food ingredients used in the foods are gluten-free prior to fermentation or hydrolysis.
- A product marked as gluten-free may be deemed misbranded under the Food, Drug, and Cosmetics Act if its manufacturer does not maintain supporting documentation to the satisfaction of the FDA.

The Food and Drug Administration (FDA) issued a new final rule (**New Rule**), which amends the existing rule governing the labeling of gluten-free foods[1] issued on Aug. 5, 2013 (**Existing Rule**). The New Rule establishes requirements for "gluten-free" labeling on fermented or hydrolyzed foods or foods that contain fermented or hydrolyzed ingredients.

A food is referred to as "fermented" if it has undergone a chemical conversion process by (1) adding certain microorganisms, such as yeast (cheese, yogurt), (2) converting sugar into ethanol (wine, spirits), or (3) producing lactic acid (pickles, sauerkraut). A food is "hydrolyzed" if it has undergone a chemical reaction using water. Examples of hydrolyzed products used in food are hydrolyzed vegetable protein and yeast extract, which are used as flavor enhancers.

Under the Existing Rule, all foods labeled as "gluten-free" must not contain a gluten-containing grain or an ingredient derived from a gluten-containing grain that exceeds 20 parts per million (ppm) of gluten. Compliance with the Existing Rule is validated by using a scientifically valid method that can detect the gluten levels in a food product.The New Rule extends the 20 ppm limitation to fermented or hydrolyzed food products that are labeled "gluten-free."

Currently, there is no scientifically valid method for detecting intact gluten in fermented or hydrolyzed foods. To address this issue, the New Rule requires manufacturers of foods that bear the "gluten-free" claim to provide adequate assurances to the FDA that the food or ingredient is gluten-free in compliance with

the Existing Rule prior to fermentation or hydrolysis. The New Rule also requires the manufacturers to maintain satisfactory documentation to this effect. In particular:

- The manufacturer must retain relevant records for 2 years after introduction or delivery of the food into interstate commerce;
- The records, whether in original or electronic form, must be made available to the FDA for inspection and copying, upon their request during an inspection; and
- The records need to be reasonably available at each manufacturing facility.

Lastly, the New Rule requires manufacturers to assess and document any potential for gluten cross-contact in its manufacturing process. If a cross-contact potential is identified, the manufacturer is required to develop and implement measures to prevent the introduction of gluten into the food during the manufacturing process.

Food manufacturers that rely on third-party gluten-free certifications should now separately confirm that their fermented and hydrolyzed foods and documentation meet the new standards.

The New Rule will become effective on Oct. 13, 2020, and has a compliance date of Aug. 13, 2021.

[1]21 CFR 101.91

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