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Food and Drug Administration (FDA) Defines 'Gluten-Free'

Article By:

Eleanor (Miki) A. Kolton

On August 5, 2013 the Food and Drug Administration (FDA) published a final rule defining the term "gluten-free" for voluntary use in food labeling. Defining the term "gluten-free" is meant to help consumers, especially those living with celiac disease, gain comfort that items labeled "gluten-free" meet a defined standard for gluten content. The compliance date for the foods labeled gluten-free is August 5, 2014.

Under the final rule, foods may be labeled "gluten-free" if they meet the definition and otherwise comply with the final rule's requirements. Specifically, the final rule defines "gluten-free" as meaning that the food either is inherently gluten free; or does 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 parts per million (ppm) or more gluten in the food.

Additionally, any unavoidable presence of gluten in the food must be less than 20 ppm.

Of note, FDA provided clarification that manufacturers are not required to test for gluten to make a gluten-free claim on their food labels.[1] The final rule does not specifically require manufacturers to test for the presence of gluten in their starting ingredients or finished foods labeled gluten-free. Nevertheless, manufacturers are responsible for ensuring that foods that bear a gluten-free claim meet the requirements of the final rule. As noted above, this means that any unavoidable gluten present in a food labeled gluten-free is less than 20 ppm.

Manufacturers may choose to use effective quality control tools to ensure that any foods they label "gluten-free" do not contain 20 ppm or more gluten, such as:

- Conducting in-house gluten testing of starting ingredients or finished foods;

- Employing a third-party laboratory to conduct in-house gluten testing;
- Requesting certificates of gluten analysis from ingredient suppliers; or
- Participating in a third-party gluten-free certification program.

Manufacturers are responsible for ensuring that their product labels are truthful and not misleading.

Background

In 2004, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of Pub. L. 108–282) directed the Department of Health and Human Services to define and permit the use of the term "gluten-free" in the labeling of foods. On January 23, 2007, the FDA published a proposed rule (see 72 Fed. Reg. 2795). The proposed rule defined the term "gluten-free" and announced FDA's intent to conduct a safety assessment for gluten exposure for people with celiac disease. In August 2011, FDA reopened the comment period on the proposal, and announced the availability of the gluten safety assessment, as well as its tentative conclusion to follow the approach in the proposed rule.

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[1] FDA "Question and Answers Gluten- Free Food Labeling Final Rule" is available here.

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