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Will an Food and Drug Administration (FDA) Rule Make People Sick? - FDA Establishes a Rule on the Labeling of "Gluten Free" Foods that Sets a Limit Above What Some Groups Claim Causes Adverse Reactions

Article By:

Food and Drug Law Group

On August 5, 2013, the U.S. Food and Drug Administration published a final rule on the labeling of foods as “gluten free.”[1] Gluten is a protein composite found in wheat, rye, barley, and their crossbred hybrids. Gluten gives elasticity to dough, helping it rise and keep its shape and often gives the final product a chewy texture. In order for a food to be labeled “Gluten Free” under the rule, the food may not contain 20 parts per million (ppm) or more gluten.[2] The rule applies to the claims “free of gluten” and “without gluten” as well.[3]

The presence of gluten is of critical importance to individuals with celiac disease. Celiac disease is an autoimmune disorder of the small intestine that occurs in genetically predisposed people. When individuals with celiac disease consume gluten, the gluten stimulates the production of antibodies and inflammatory cells, resulting in an abnormal immune response. The symptoms and clinical manifestations of celiac disease are highly variable among affected individuals and differ in severity.

In drafting the rule, FDA was faced with four options on establishing a threshold level:

- Analytical methods-based, where the threshold is determined by available analytical method sensitivity
- Safety assessment-based, where the threshold is determined using the No Observed Adverse Effect Level (NOAEL) from available human challenge studies
- Risk assessment-based, where the threshold is established based on known or potential adverse health effects resulting from human exposure, quantified by the levels of risk associated with specific exposures and the degree of uncertainty inherent in the risk estimate
- Statutorily derived, where the threshold is extrapolated from an applicable law.[4]

Among these four options, FDA’s decided to rely largely on the available analytical methods. The

risk-assessment and statutory methods were determined to be inappropriate under the circumstances. FDA also evaluated a safety assessment based approach. One of the issues noted in FDA's decision to use the analytical methods-based criteria was harmonizing with international trading partners such as Canada and the European Union, which use a standard of no greater than 20 ppm gluten for gluten-free claims.

One of the key complaints among the celiac disease community with the 20 ppm standard is that even at this threshold, the amount of gluten adds up quickly. FDA calculates that, at a concentration level of 20 ppm gluten, a 1-ounce portion of food (28.35 grams) or would contain 0.567 milligrams (mg) of gluten. Because 20 ppm refers to a concentration and not an absolute quantity of gluten, this can be additive. Assuming a daily intake of 70 ounces of food, if all of the food contained 20 ppm of gluten, the daily intake would be almost 40 mg of gluten. Research by the University of Maryland's Center for Celiac Research found that consumption of 50 mg per day of gluten would cause villous atrophy after 90 days, and that one patient developed villous atrophy after 90 days of consumption of 10 mg of gluten per day.[5]

Being an analytical methods-based threshold level leaves open the possibility that as analytical methodology provides greater sensitivity at lower cost, FDA may consider lowering the threshold level. There is documented dissatisfaction in the celiac community regarding FDA's choice of an analytical methods-based threshold.[6] Certainly, manufacturers that are interested in marketing to the gluten-free community should focus on ensuring the absence of gluten in food through scrupulous good manufacturing and purchasing controls. Several independent organizations provide gluten free certification for suppliers and manufacturers. While this certification is currently included on some labeling, FDA notes that it "will evaluate such labeling to ensure such information is truthful and not misleading and meets other applicable FDA requirements."[7]

The attorneys at Sheppard Mullin Richter & Hampton LLP have extensive experience in both good manufacturing practices surrounding commercial food production, and in labeling issues. Our intimate knowledge regarding the background on FDA's gluten free rule is important for any food manufacturer.

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[1] FDA, Final Rule, "Food Labeling; Gluten-Free Labeling of Foods," 78 Fed. Reg. 47,154 (Aug. 5, 2013).

[2] 21 C.F.R. § 101.91(a)(3).

[3] Foods that inherently do not contain gluten;-such as dairy, may also be so labeled.

[4] FDA, Final Rule, "Food Labeling; Gluten-Free Labeling of Foods," 78 Fed. Reg. 47,154, 47,156 (Aug. 5, 2013).

[5] Jane Anderson, *How much gluten can make me sick?* (Jan. 28, 2013), at http://celiacdisease.about.com/od/PreventingCrossContamination/f/How-Much-Gluten-Can-Make-Me-Sick.htm.

[6] Peter Olins and Gillian Olins, *Proposed FDA Standard for Gluten-Free Foods (20 ppm) May Not Adequately Protect the Food Supply for Celiacs*(Aug. 18, 2011), at http://ultimateglutenfree.com/2011/08/fda-20-ppm-regulation-gluten-free-food-celiac-disease/.

[7] FDA, Final Rule, "Food Labeling; Gluten-Free Labeling of Foods," 78 Fed. Reg. 47,154, 47,161 (Aug. 5, 2013).

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