Changes in Gluten-Free Labeling: A Closer look at TTB and FDA Regulations

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Introduction

To date, the regulatory environment for gluten-free labeling on food and alcohol products has been nebulous to say the least. With undefined standards for voluntary disclosure, regulatory compliance has been a challenge for manufacturers and distributors, and has likewise made consumers wary of the reliability and scientific accuracy of such claims.

Celiac diease (CD) is a serious autoimmune disorder characterized by the body's immune response to proteins in wheat and other grains. It affects roughly one in 266 people worldwide and one in 133 in the United States.[1] Millions affected with CD rely on gluten-free labeling to make diet choices, in addition to those who seek the medical benefits associated with a gluten-free diet.[2] In individuals with CD (also known as celiac sprue and gluten sensitive enteropathy), the consumption of wheat gluten and similar proteins in barley and rye stimulates the production of antibodies and inflammatory cells, resulting in an abnormal immune response.[3] The immediate inflammatory reaction damages the tiny, fingerlike protrusions called "villi" that line the small intestine and absorb nutrients from food, as continued dietary exposure to gluten from wheat, barley, or rye can result in long-term impaired absorption of nutrients and a host of additional serious health concerns, including reduced bone density (osteopenia and osteoporosis), anemia, increased

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risk of other autoimmune disorders and malignancies, infertility and neurological problems.[4] Currently, there is no cure or treatment for CD, apart from a lifelong, strict gluten-free diet.

Accordingly, the demand for gluten-free products has naturally resulted in a growing $2.6 billion market.[5] While the voluntary international food code, Codex Alimentarius, and the European Union have issued updated gluten-free standards,[6] the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) and Food and Drug Administration (FDA) are stepping right behind in implementing updated rulings. These updates are critical in an area where scientific uncertainty and methodology in establishing a "safe" threshold amount, currently at at an FDA established standard of twenty per million (ppm) which may not be optimal for those suffering with CD.

Regulation of Gluten-Free Labeling with Respect to Food Products

Recognizing the need for a uniform definition of "gluten-free" to alleviate the pervasive concerns with confusing labels, provide clear ingredient disclosure on food labels and protect consumer health, Congress imposed ingredient and disclosure requirements through the Food Allergen Labeling and Consumer Protection Act of 2004.[7]

FDA subsequently issued a proposed rule in the *Federal Register,* 72 Fed. Reg. 2795, on January 23, 2007, to define the term "gluten-free" for voluntary use in the labeling of foods, to mean that the food does not contain any of the following:

An ingredient that is any species of the grains, wheat, rye, barley or a crossbred hybrid of these grains (all noted grains are collectively referred to as "prohibited grains");

1. *an ingredient that is derived from a prohibited grain and has not been processed to remove gluten (e.g., wheat flour);*
2. *an ingredient that is derived from a prohibited grain and has been processed to remove gluten (e.g., wheat starch) if the use of that ingredient results in the presence of twenty parts ppm or more gluten in the food*[8]

Under the proposed rule, a food that bears the claim "gluten-free" or similar claim in its labeling and fails to meet the conditions specified above would be deemed misbranded. FDA also is proposing to deem misbranded a food bearing a gluten-free claim in its labeling the food is inherently free of gluten and if the claim does not refer to all foods of that same type. FDA's position is consistent with its regulations governing the use of other "free" claims; FDA has issued regulations governing the use of other "free" claims, which provide that "calorie-free," "sodium-free," "fat-free," and "cholesterol-free" labeling claims made for a food that is inherently void of these substances is misleading to consumers without additional clarifying language to demonstrate that all foods of the same type, not just the brand of food bearing that "free" labeling claim, are also free of the stated substance.

1. an ingredient that is any species of the grains wheat, rye or barley or a crossbred hybrid of these grains (collectively referred to as "prohibited grains");

   Accordingly, FDA is proposing that with the exception of a food made from oats, any food that is naturally free of gluten may bear the claim "gluten-free" provided both of the following requirements are met:
2. The wording of the claim clearly indicates that all foods of the same type, not just the brand bearing this labeling claim, are gluten-free (e.g., "milk, a gluten-free food," "all milk is gluten-free)
3. The food does not contain 20 ppm or more gluten.

These regulations have not been finalized and are therefore not in effect, meaning that "gluten-free" labels do not yet have to comply with the above requirements. Should a final rule be issued- and it is unclear at this point if and when that may happen- it is expected that FDA will allow for a transition period of 12-48 months for industry to comply with the new labeling rules.

Regulation of Gluten-Free Labeling with Respect to Alcohol

The Federal Alcohol Administration Act (FAA Act) provides for regulation of the labeling and advertising of distilled spirits, wine, and malt beverages.[14]

This law gives the Treasury Secretary the authority to issue regulations intended to prevent deception of the consumer, provide the consumer with adequate information as to the identity and quality of the product, and prohibit false or misleading statements.[15] Additionally, the law provides the Treasury secretary with the authority to prohibit, irrespective of falsity, statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer.[16] Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of

the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d).[17]

On May 24, 2012, the TTB issued an Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages.[19] Pending the issuance of a final rule by FDA, TTB is providing interim guidance on the use of the term "gluten free" on alcohol beverage labels and advertisements subject to TTB's authority.[20]

a. Alcohol Products Made from Gluten-Free Materials

TTB's position is that the term "gluten-free" will be interpreted by consumers of alcohol beverages to mean that the product contains no gluten.[21] TTB provided the example of wine fermented from grapes, or vodka distilled from potatoes.[22] If there are good manufacturing practices – meaning no cross-contamination, no additives, no yeast, and no storage materials with gluten – a 'gluten-free' claim in the labeling of the alcohol beverage will be permissible in the interim period awaiting FDA's ruling.[23]

b. Alcohol Products Made from Gluten-Containing Materials

FDA and TTB both assert that there are currently no scientifically valid testing methods to determine the gluten content of fermented products.[24] As a result, TTB's position is that processes that may be undertaken by beverage companies to remove the gluten from their alcoholic beverages...[25]

TTB's position is that these methods cannot be used to substantiate a "gluten-free" claim at this time.[26] Further, a "gluten-free" statement on labeling for a product made from gluten would be misleading.[27]

However, the following statement is permissible: "Processed/Treated/Crafted to Remove Gluten".[28] This statement must be accompanied with the following conspicuous qualifying statement: "Product fermented from grains containing gluten and [processed or treated or crafted] to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten.", or "[T]his product was distilled from grains containing gluten, which removed some or all of the gluten. The gluten content of this product cannot be verified, and this product may contain gluten."[29]

Conclusion

As recognized by the Consumer Health Information for Better Nutrition Initiative, "[i]n order for consumers to make healthy dietary choices across product categories, consistency in health messages is paramount."[30] As current labeling and proposed changes still run the risk of gluten-free label inaccuracy (i.e., some CD patients may still believe "gluten-free" means zero-gluten), FDA should engage in worthwhile discussion of disclaimer mandates to reduce consumer confusion. "The disclaimer could be simple wrote Professor Margaret McCabe of Franklin Pierce Law Center. Any product labeled gluten-free product could simply state on its label: 'This product contains no more than 20 ppm gluten, verified using FDA-approved testing methods.'[31] With improvements in testing methodology, the threshold disclaimer could become lower if warranted. As McCabe notes, linking labeling to a threshold would ensure that disclaimers to help consumers locate appropriate products (e.g., if science determines a gluten-free diet may improve autism at a lower threshold of 10 ppm).[32] Such information disclosures would permit consumers to calculate risks based on personal sensitivities that are incapable of being ascertained with a label that may categorically read "gluten-free". ⚠

1. *Available at* http://www.celiacdiseasecenter.org/A_Patients/A02-FAQ.htm (last visited Sept. 24, 2012).
2. 65 Food Drug L.J. 367 (2010).
3. 76 F.R. 79196.
4. *Id*.
5. 65 Food Drug L.J. 367, 368 (2010).
6. Commission Regulation No. 41/2009, Concerning the Composition and Labeling of Foodstuffs suitable for people intolerant to gluten, 2009 O.J. (L16) 3 (Jan. 21, 2009; Codex Alimentarius Commission, Standard for Special Dietary Use for Persons Intolerant to Gluten, Stan. 118-1979 (as amended 1983, 2009) *available at*: http://www.codexalimentarius.net/web/standard_list.jsp (last visited Sept. 24, 2012) [hereinafter Codex Stan. 118-1979]; *see also* Codex General Standard for the Labeling of Prepackaged Foods, Stan. 146-1985, *available at*: http://www.codexalimentarius.net/web/index_en.jsp (last visited Sept. 24, 2012).
7. FALPCA, Title II, Pub. L. No. 108-282, 118 Stat. 891 (2004) [hereinafter FALCPA or cited as appropriate to the *United States Code*].
8. *See* 73 F.R. 2795 (Jan. 23, 2007); 76 F.R. 46671 (Aug. 3, 2011).
9. *See* § 101.60(e)(ii) (21 C.F.R. § 101.60(e)(ii)).
10. *See for example*, sodium e.g., § 101.61(b)(1)(iii) (21 C.F.R. § 101.61(b)(1)(iii)).
11. *See* § 101.62(b)(1)(iii) (21 C.F.R. § 101.62(b)(1)(iii)),
12. *See for example*, cholesterol, § 101.62(d)(1)(ii)(E)).
13. 72 F.R. 2795.
14. 27 U.S.C. §§ 205(e), 205(f).
15. *Id*.
16. *Id*.
17. *See* 6 U.S.C. § 531(d).
18. U.S. Treas. Order No. 120-01(Jan. 24, 2003), *available at* http://www.treasury.gov/about/role-of-treasury/orders-directives/Pages/to120-01.aspx (last visited Sept. 7, 2012).
19. TTB Ruling No. 2012–2 (May 24, 2012) *available at* http://www.ttb.gov/rulings/2012-2.pdf (last visited Sept. 7, 2012) [hereinafter TB Interim Gluten Rule].
20. *Id*.
21. *Id*.
22. *Id*.

23. *Id*.
24. TB Interim Gluten Rule, *supra* note 18.
25. *Id*.
26. *Id*.
27. *Id*.
28. *Id*.
29. TB Interim Gluten Rule, *supra* note 18.
30. FDA, Consumer Health Information for Better Nutrition Initiative Task Force, Final Report (Jul. 10, 2003) *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/QualifiedHealthClaimsPetitions/ucm096010.htm (last visited Sept. 24, 2012).
31. 65 Food Drug L.J. 389 (DATE).
32. *Id*.