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FDA Releases Proposed Rule Defining Standard for "Gluten-Free" Labeling Claims

FDA recently released a proposed rule¹ defining the term "gluten" and a standard for when a "gluten-free" claim may be made on food labels. FDA issued the proposed rule in response to a mandate in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA),² an Act that requires that uniform, plain English terminology be used in ingredient labeling to declare the presence of eight major food allergens (defined as wheat, milk, egg, fish, crustacean shellfish, tree nuts, peanuts, and soybeans). The FALCPA also directed FDA to issue a proposed rule by August 2, 2006, defining and permitting voluntary use of the labeling claim gluten-free, and issue a final rule by August 2, 2008.³ FDA is accepting comments on this proposed rule through April 23, 2007.

The proposed rule is intended to help the estimated 1.5 to 3 million Americans with a chronic inflammatory disorder of the small intestine called celiac disease, which can cause a variety of serious health problems and for which the only treatment is dietary avoidance of gluten (proteins found in certain cereal grains that are harmful to individuals with celiac disease). Although several countries have adopted definitions of the term gluten-free, currently there is no regulatory definition of the term in the United States,⁴ and no clear consensus about the meaning of the term among industry, consumer, and other stakeholder groups.

I. Proposed Definition of "Gluten" and Standard for "Gluten-Free" Claims

The proposed rule would define the term "gluten" to mean "the proteins that naturally occur in a 'prohibited grain' and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins)."⁵ "Prohibited grain" would be defined to mean any species of the grains wheat (meaning any species belonging to the genus *Triticum*), rye (meaning any species belonging to the genus *Secale*), barley (meaning any species belonging to the genus *Hordeum*), and any crossbred hybrid of these grains.⁶ All other grains, including oats and millet, are not included.

¹ The proposed rule, 72 Fed. Reg. 2,795 (Jan. 23, 2007), is available at <http://www.cfsan.fda.gov/~lrd/fr070123.html>. FDA also released a related guidance document, entitled "Questions and Answers on the Gluten-Free Labeling Proposed Rule" (Jan. 23, 2007), which is available at <http://www.cfsan.fda.gov/~dms/glutqa.html>.

² Public Law 108-282, Title II, available at <http://www.cfsan.fda.gov/~dms/algact.html>.

³ FALCPA § 206; 21 U.S.C. § 343(note).

⁴ In the preamble to a final rule concerning the declaration of ingredients on food packaging published in 1993, FDA stated that the term gluten-free is permissible in labeling so long as it is not "false or misleading" – a regulation that has been difficult to implement without a definition of "gluten-free." 58 Fed. Reg. 2,850, 2,864 (Jan. 6, 1993). *See also* 72 Fed. Reg. at 2,799 (In the 1993 preamble, FDA advised that "[g]enerally, and absent regulations to the contrary, FDA would regard a claim that a food is 'free' of a substance as false or misleading if the food contains that substance. FDA also noted that the term 'gluten-free' may be misleading when the food ordinarily does not contain gluten.").

⁵ Proposed 21 C.F.R. § 101.91(a)(2); 72 Fed. Reg. at 2,817.

⁶ Proposed 21 C.F.R. § 101.91(a)(1); 72 Fed. Reg. at 2,797.

Under the proposed rule, food labeling would be permitted to bear the claim “gluten-free” only if all six of the following requirements were met:

1. The food does not contain an ingredient that is a prohibited grain. (Examples include wheat, barley, rye, durum wheat, spelt wheat, einkorn wheat, emmer wheat, kamut, and triticale.)
2. The food does not contain an ingredient that is derived from a prohibited grain and has not been processed to remove gluten. (Examples include, but are not limited to, farina, graham, semolina, hydrolyzed wheat protein, vital gluten, wheat bran, wheat germ, barley malt extract, and malt vinegar.)
3. The food does not contain an ingredient that is derived from a prohibited grain and has been processed to remove gluten, if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food. (Examples include, but are not limited to, wheat starch and modified food starch.)
4. The food does not contain 20 ppm or more gluten, for any reason.⁷
5. If the food is made from oats, the claim does not suggest that all foods made from oats are gluten-free, and the product does not contain 20 ppm or more gluten.⁸ (This regulation governs oats, any food that contains oats, and any food that contains any ingredient derived from oats.)
6. If the food is inherently free of gluten, then the claim must so indicate and must not contain 20 ppm or more gluten.⁹ (Examples of foods inherently free of gluten include, but are not limited to, unflavored milk, 100 percent fruit or vegetable juices, fresh fruits and vegetables that are not coated with a wax or resin that contains gluten, butter, lentils, peanuts, soybeans, seeds, tree nuts, corn, rice, fresh fish, honey, and water. Examples of permissible claims for such food include “milk, a gluten-free food” or “all milk is gluten-free.”)

II. Key Aspects and Implications of the Proposed Rule

- *Labeling is voluntary:* Unlike the FALCPA labeling scheme for big eight allergens, gluten-free labeling is permissive, not mandatory. A manufacturer would be required to comply with FDA's regulation concerning the standard for gluten-free claims only if the manufacturer voluntarily chose to make this claim on a product. Further, the gluten-free claim is not intended to be a claim for special dietary use, a nutrient content claim, or a health claim, with their associated requirements for use.¹⁰

⁷ Proposed 21 C.F.R. § 101.91(a)(3); 72 Fed. Reg. at 2,802.

⁸ Proposed 21 C.F.R. § 101.91(b)(3); 72 Fed. Reg. at 2,802.

⁹ Proposed 21 C.F.R. § 101.91(b)(2); 72 Fed. Reg. at 2,802.

¹⁰ S. Rep. No. 108-226 (2004), at 11.

- *Analytical testing would likely be needed:* In contrast with the FALCPA's labeling scheme for big eight allergens, which reflects an ingredients-based approach to allergen labeling, the proposed rule would adopt both an ingredients-based and an analytical testing-based standard for use of the term gluten-free. The proposed gluten-free regulation would permit manufacturers to use the gluten-free claim only if they determine that no ingredient purposefully added to a product contains gluten and that the product does not contain 20 ppm or more gluten. The proposed rule would thus prohibit a food from bearing a gluten-free claim if gluten were present at 20 ppm or more due to co-mingling or cross-contact with gluten at any point during the farm-to-table process (e.g., harvesting, transporting, storage, processing, etc.). This would mean that even if no gluten-containing ingredients were added to a product, a manufacturer might need to establish and implement protocols for analytical testing to ensure that less than 20 ppm of gluten is present in a finished product.¹¹
- *Oats are not per se prohibited:* There is longstanding scientific controversy about whether individuals with celiac disease may safely consume oats. Some evidence suggests that oats may be harmful to a small percentage of individuals with celiac disease and that some oats may contain gluten due to co-mingling with gluten-containing grains.¹² FDA concludes that, because the potential nutritional and dietary benefits of oats to people with celiac disease is substantial, and moderate consumption of oats that have not co-mingled with gluten-containing grains is likely to be safe for the majority of people with celiac disease, excluding oats from the proposed definition of "prohibited grain" is consistent with the public health policy objectives of the FALCPA. FDA thus proposes to allow "gluten-free" claims for oat-containing products that contain less than 20 ppm gluten.¹³
- *Authorized "gluten-free" synonyms:* Other terms in addition to "gluten-free" would be permitted when the above six criteria for gluten-free claims are met. FDA advises in guidance that permissible synonyms would be confined to "free of gluten," "without gluten," and "no gluten."¹⁴
- *Standard does not apply to foods regulated by USDA:* The proposed rule would apply only to food subject to regulation by FDA under the Federal Food, Drug, and Cosmetic Act. The standard would not apply to meat, poultry, and egg products which are subject to regulation by USDA under the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act.

¹¹ FDA declined to propose a standard that would simply prohibit gluten-free claims for food products containing 20 ppm or more gluten. FDA concluded that such a standard would require more analytical testing and therefore entail greater enforcement costs than the proposed standard, which can in some cases be enforced through on-site inspections and label examinations rather than sample analysis. 72 Fed. Reg. at 2,804-05, 2,812.

¹² 72 Fed. Reg. at 2,798.

¹³ *Id.* at 2,798-99.

¹⁴ Questions and Answers on the Gluten-Free Labeling Proposed Rule, Question # 12.

III. Possible Change in the Final Rule

FDA has indicated that it may change the level of gluten permitted in a food labeled gluten-free (currently 20 ppm) in the final rule. An important scientific issue associated with the definition of gluten-free is the potential existence of a threshold level below which it is unlikely that an individual with celiac disease would experience adverse health consequences. In response to an FDA working group that reviewed the scientific literature concerning a threshold level for gluten and an advisory committee meeting evaluating the issue, FDA determined that there is currently insufficient data to establish a threshold level based on the risk to people with celiac disease posed by different levels of gluten.¹⁵ Instead, FDA based the proposed threshold level on available gluten detection methods. FDA states in the preamble that present analytical methods can reliably and consistently detect gluten only at 20 ppm or above.¹⁶

The agency indicates that it may be appropriate to lower the threshold level as new, more sensitive methods of gluten detection are developed.¹⁷ Further, FDA intends to conduct a safety assessment for gluten to estimate a “safe” level of gluten exposure, and to consider the safety assessment and comments received on the proposed rule when developing the final rule.¹⁸

IV. Legal Risk Management Issues

FDA makes clear in the preamble to the proposed rule that failure of a product labeled gluten-free to comply with the gluten-free standard that would be adopted in a final rule could cause the product to be deemed misbranded. FDA intends to enforce the gluten-free standard through firm inspections, label reviews, and when necessary, analytical testing of food samples. In addition, it is likely that any labeling standard that FDA establishes, and the threshold it embodies, may be cited as the standard by which representations concerning gluten that manufacturers and restaurants make to consumers should be evaluated.

For companies marketing food products designed for consumers with celiac disease, the FDA proposed definitions of “gluten,” “prohibited grains,” and other provisions could have regulatory compliance and product liability implications for promotional claims made not only in labeling, but advertising and promotions more generally under both the Federal Trade Commission Act and state consumer protection statutes.¹⁹ Companies may wish to consider the broader food marketing related legal risk management issues presented in developing comments for submission to FDA concerning its proposal. Covington & Burling LLP is experienced in legal matters concerning the development and defense of food marketing programs and promotional claims under federal and state laws, and is available to assist companies in developing comments on the FDA proposal, and to provide individualized legal risk management counseling concerning food formulation and marketing issues.

¹⁵ 72 Fed. Reg. at 2,803. See also Threshold Working Group, Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food (Mar. 2006), Docket No. 2005N-0231, available at <http://www.cfsan.fda.gov/~dms/wh-alty.html>

¹⁶ 72 Fed. Reg. at 2,803.

¹⁷ *Id.* FDA notes that it would consider whether the adoption of a lower threshold level would in fact benefit individuals with celiac disease, however, before doing so.

¹⁸ *Id.*

¹⁹ See, e.g., Federal Trade Commission, Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388 (June 1, 1994) (stating the Commission’s policy to generally look to standards set by the FDA’s food labeling regulations to evaluate whether nutrient content and health claims in advertising are deceptive).

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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