

Tips For Restaurants (And Counsel) In A Gluten-Free World

Law360, New York (August 22, 2014, 4:53 PM ET) --

On Aug. 5, 2014, the U.S. Food and Drug Administration's final regulatory definition of the terms "gluten-free," "no gluten," "free of gluten," or "without gluten" took effect, meaning that food sellers — including restaurants — who elect to make use of this voluntary term on their labels or menus must ensure that foods bearing that phrase contain 20 ppm or less of gluten. Many food industry players want a piece of the \$10.5 billion pie of the gluten-free food sector.[1] Counsel who advise food sellers and restaurants that are considering use of "gluten-free" labels should educate themselves and their clients on several key issues pertinent to this decision.



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What is Gluten, Anyway?

Gluten is a starchy protein found in grains that triggers an immune response and causes intestinal inflammation for those with celiac disease. Eating a gluten-free diet helps celiac sufferers control their symptoms by avoiding foods such as: breads, cakes, cereals, cookies, French fries, beer, pastas, sauces, etc. — unless they are sourced from gluten-free substances and manufactured in gluten-free environments.

Why Does the Food Industry Care About Gluten-Free Products?

Besides those with celiac disease, a staggering number of Americans are associating the term "gluten-free" as "healthier" or somehow "better" than traditional foods. Twenty-three percent of Americans claim to avoid gluten consumption due to non-celiac gluten concerns.[2] U.S. retail sales of gluten-free products surged 47 percent in 2013.[3] "From a marketing angle, avoiding gluten is on track to become more widespread than the low-carbohydrate diet, championed by Dr. Robert Atkins." [4] "Any trend is a marketing opportunity." [5] "The [gluten-free] category is big business." [6]

Why Should Restaurants Care About Gluten-Free Food?

Gluten-free interest at restaurants is now more than double what it was four years ago, accounting for over 200 million visits last year.[7] "The number of U.S. adults who say they are cutting down on or avoiding gluten is too large for restaurant operators to ignore," says NPD restaurant industry analyst Bonnie Riggs.[8]

What Does "Gluten-Free" Mean?

What qualifies a food to earn the “gluten-free” label in the first instance?

The FDA’s August 2013 final regulatory definition of the terms “gluten-free,” “no gluten,” “free of gluten,” or “without gluten” for sellers’ voluntary use in labeling sets the same gluten threshold for everyone in the industry: such labeled foods must “not contain an ingredient that is a gluten-containing grain; an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or an ingredient that is derived from a gluten-containing grain and 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 (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or inherently does not contain gluten; and that any unavoidable presence of gluten in the food is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food).” 21 C.F.R. 101.91(a)(3). The FDA gluten-free rule does not require testing products for trace gluten and does not budget money for aggressive FDA policing and enforcement of the gluten-free definition.

FDA-regulated foods and beverages (e.g., packaged foods, dietary supplements, fruits, vegetables, shell eggs and fish) labeled “gluten-free” must comply by Aug. 5, 2014, with all requirements established by the final rule, or else be deemed misbranded and subject to regulatory enforcement action.

The FDA’s “Gluten-Free” Definition Applies to Restaurants

The FDA expects restaurants serving food labeled “gluten-free” to meet the 20 ppm standard as of the Aug. 5, 2014, compliance date. See FDA’s December 2013 website Question & Answer section.[9]

Is the Label Worth it to Your Client?

Effective counseling of restaurant clients will include a discussion with them of “non-ppm” issues and a suggestion that the restaurant client seriously evaluate whether the risks and costs of using this menu label outweigh the benefits. Remind clients that there are legal, marketing and revenue concerns if a restaurant voluntarily elects to use the “gluten-free” label on menu items, such as:

- The time involved in sourcing verifiably gluten-free ingredients;
- Capital investment in additional kitchen equipment to reduce the risk of gluten cross-contamination (even from airborne gluten the size of a sand grain) during cooking;
- Development of recipe variations for menu items to substitute non-gluten ingredients (e.g., use of fewer processed ingredients, which tend to have less risk of trace gluten);
- Standardizing gluten-avoidance cooking procedures across multiple restaurant locations;

- Creating, implementing and monitoring consistent adherence to back- and front-of-house employee training programs for gluten-free food handling protocols;
- Sourcing ingredients from suppliers that are reliably gluten-free (which might be easier for large chains than local restaurants);
- Education of restaurant staff and purchasing departments about the presence of gluten in foods that do not necessarily say “gluten” (e.g., malt, malt vinegar, barley, rye);
- Risk of FDA enforcement action if a labeled menu item transgressed the 20 ppm limit;
- Damage to business reputation from loss of consumer goodwill if labeled menu items actually contain offending levels of gluten from such items’ own cooking process or from kitchen cross-contamination with regular menu items;
- Adverse publicity and possible regulatory investigation if a customer reports adverse health effects to the Center for Food Safety and Applied Nutrition’s Adverse Event Reporting System;
- Negative press and possible regulatory action if a patron submits a complaint to an FDA Complaint Coordinator in the state where the food was purchased;
- Personal injury and/or consumer fraud claims by celiac sufferers who partake of definition-noncompliant menu items in reliance on their designation as “gluten-free” on the menu; and
- Enforcement action by local health departments (at the FDA’s directive[10]).

With these risks, there must be careful consideration of whether the additional costs, time and labor to offer gluten-free items translate into profits that justify the investment and into increased long-term goodwill from consumer beliefs in the restaurant’s concern for their health and safety. Restaurant counsel should focus clients’ attention on these the behind-the-scenes business considerations to contemplate before stamping menu items “gluten-free.”

Breadcrumbs of Guidance to FDA-Compliant Gluten-Free Menu Labels

If a restaurant decides that the benefits of gluten-free labeling outweigh the costs, its attorney need not worry that Gluten 101 was not covered in law school. There is a menu of options to help restaurant-clients achieve FDA-compliant use of the voluntary “gluten-free,” including: (1) in-house gluten education training; and (2) third-party independent “gluten-free” certification.

On June 25, 2014, the FDA issued a guide for small food businesses to help them comply with its Aug. 5, 2013, definition[11]: “The rule does not require you to test for the presence of gluten in your starting ingredients or finished foods labeled ‘gluten-free.’ However, you are responsible for ensuring that foods bearing a gluten-free claim meet our requirements, including that any unavoidable gluten present in a food labeled gluten-free is less than 20 ppm. We encourage you to use effective measures to ensure that any foods labeled as ‘gluten-free’ comply with our requirements; such measures may include: [a] testing the ingredients to determine their gluten content; [b] requesting certificates of gluten analysis from ingredient suppliers; or [c] participating in a third-party gluten-free certification program.”[12]

(1) In-house Training About “Gluten-Free”

Nonprofit National Foundation for Celiac Awareness offers GREAT Kitchens (Gluten-free Resource Education and Awareness Training)[13], an online, self-managed and bilingual 90-minute multimedia course for chefs, foodservice managers, and restaurant staff to teach gluten-free food preparation and handling. GREAT Kitchens educates management on practical issues such as: the many possible origins of gluten in food sourcing and preparation; the time, financial and personnel training investment needed to develop and implement food handling protocols to reduce cross-contamination risk; and a robust sense of the levels of detail involved in committing a food service operation to the FDA’s gluten-free definition. Training program costs range[14] from \$25.00 for Basics courses to \$100 for Management.

(2) Gluten-Free Food Certification

Several organizations offer gluten-free food certification that enables customers to trust menu items labeled “gluten-free.” Each certification body has its own gluten level standards and certification costs:

(A) The Gluten-Free Certification Program certifies foods that test to gluten levels at 10 ppm or less, recognizing their standard is more stringent than the FDA’s.[15] GFCP’s certification does end-product testing and examines a facility’s entire production process, including ingredient sourcing, employee training, cleaning practices, cross-contamination controls and operational management.[16] Their certification involves: (1) \$499/facility application fee and annual licensing fees for use of GFCP’s trademark; (2) audit fees payable to a third-party company approved by the Allergen Control Group; and (3) consulting/training support.[17]

(B) Nonprofit The Gluten Intolerance Group’s certification program is a yearly process (based on ingredient review, on-site inspection and ongoing on-site product testing) that uses quality assessment and control measures throughout food production. Their certification standard is 10 ppm or less.[18] Product certification is valid for one year and renews annually. Costs include: (1) \$500 audit fee per site; (2) inspector travel expenses; and (3) flat-rate licensing/certification fee based on risk and number of sites. These costs will vary depending on the manufacturing environment and site complexity.”[19]

(C) Healthy Dining offers gluten assessment to identify which of a restaurant’s ingredients, recipes,

preparation methods and menu items contain gluten.[20]

(D) MenuTrinfo and sister company Kitchens With Confidence offer gluten-free menu item certification and gluten-free training.[21] According to their website, their menu certification program analyzes menus; sources ingredients and speaks with manufacturers about possible cross-contamination; checks for hidden sources of gluten; and creates a Certified Gluten-Free Menu with MenuTrinfo's seal of confidence. In their gluten-free training program, two restaurant supervisory staff members attend an AllerTrain online certified class to learn how to offer gluten-free menu items, including proper back-of-house as well as front-of-house procedures. They offer in-person or online customized classes, starting at \$19 for AllerTrain Lite (a condensed version). Clients can pay for a single seat in an online class or a group price.[22] MenuTrinfo's live 90-minute webinar AllerChef program provides training for chefs on how to make gluten-free menu items.

(E) Celiac Support Association offers gluten-free certification through its CSA Recognition Seal and requires that foods yield less than 5 ppm gluten. CSA says its Recognition Seal[23] is "reserved for the 'Best of the Best.'"[24] For example, foods may contain non-cross-contaminated oats under the FDA definition, but not under CSA's program.[25] The CSA Recognition Seal costs: (1) \$500 start-up fee for first year; (2) \$40 per item for testing; and (3) annual fees to retain seal in subsequent years, with fee amounts based on a percentage of sales of the food item bearing the seal.

(F) NSF International offers a Gluten-Free Certification Program that, according to its website, uses "sensitive testing procedures, a stringent auditing process, on-site annual inspections and testing, and an independent application review process to validate the accuracy of gluten-free labels." [26] NSF certification involves: (1) product and current procedures review; (2) on-site inspection; (3) random on-site food sample testing to 10 ppm or less gluten; (4) certification; and (5) ongoing compliance via annual inspections.

Conclusion

For restaurants to have their gluten-free cake and eat it too when it comes to capitalizing on the use of "gluten-free" menu labels, their counsel should have a dialogue with the client about all of the details that are necessary to ensure that every facet of their operations — e.g., sourcing, food handling, cooking, front-of-house staff answering diners' questions — are providing foods compliant with the FDA's definition of "gluten-free." This dialogue is also necessary to make certain the clients' expectations going into the gluten-free world are realistic and not caught off guard from the level of commitment required, such as from: application fees, audit costs, site inspection charges, menu reconsideration, ingredient sourcing review, separate equipment to prevent gluten cross-contamination, business interruption during certification review, food testing costs, and training. Lawyers can help their food seller and restaurant clients decide whether the profits to come from menu labels that tout gluten-free entrees outweigh the costs of that label within the limits of the FDA's definition.

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[1] October 14, 2013 Mintel market research report (<http://www.mintel.com/press-centre/food-and-drink/gluten-free-food-to-lose-weight>); "Gluten-free offerings: Grains of truth," Lisa Jennings (Nation's Restaurant News, June 11, 2012) (<http://nrm.com/health-amp-nutrition/gluten-free-offerings-grains-truth>).

[2] "56% of U.S. shoppers say they are cutting back on white bread, says Packaged Facts," Elaine Watson (January 30, 2014, FoodNavigator USA) (citing Packaged Facts June 2013 survey) (<http://www.foodnavigator-usa.com/Markets/56-of-US-shoppers-say-they-are-cutting-back-on-white-bread-says-Packaged-Facts>).

[3] "Half of new product sales in gluten-free are from snacks, but are we close to saturation point?," Elaine Watson (FoodNavigator USA, July 17, 2014) (<http://www.foodnavigator-usa.com/Trends/Gluten-free/Half-of-new-gluten-free-product-sales-in-US-are-from-snacks>).

[4] "Gluten-Free Eating Appears To Be Here To Stay," Kim Severson (New York Times, June 16, 2014) (http://www.nytimes.com/2014/06/18/dining/gluten-free-eating-appears-to-be-here-to-stay.html?_r=0)

[5] "Gluten Takes A Beating From Fad Dieters and Grain Giants," Matthew Boyle (Bloomberg News, November 12, 2013) (quoting Nicholas Fereday, an analyst at Rabobank) (<http://www.bloomberg.com/news/2013-11-12/grain-giants-go-gluten-free-to-plump-profits-on-fad-diet.html>)

[6] "Why We're Wasting Billions on Gluten-Free Food," Martha C. White (Time Business, March 13, 2013) (<http://business.time.com/2013/03/13/why-were-wasting-billions-on-gluten-free-food/>)

[7] "Percentage of U.S. Adults Trying to Cut Down or Avoid Gluten in Their Diets Reaches New High in 2013, Reports NPD" (NPD Group's Dieting Monitor, March 6, 2013) (<https://www.npd.com/wps/portal/npd/us/news/press-releases/percentage-of-us-adults-trying-to-cut-down-or-avoid-gluten-in-their-diets-reaches-new-high-in-2013-reports-npd/>) ("As of this January about a third of U.S. adults say they want to cut down or be free of gluten in their diets, the highest percentage making this claim since NPD Group began asking the question in 2009").

[8] "One in Three Americans Now Avoiding Gluten," April 5, 2013 (celiac.com) (quoting Bonnie Riggs) (<http://www.celiac.com/articles/23241/1/One-in-Three-Americans-Now-Avoiding-Gluten/Page1.html>)

[9]
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm362880.htm>

[10] "[S]tate and local governments play an important role in oversight of restaurants. We expect to work with our state and local government partners with respect to gluten-free labeling in restaurants. We will consider enforcement action as needed, alone or with other agencies, to protect consumers." (<http://www.fda.gov/food/resourcesforyou/consumers/ucm367654.Htm>)

[11]
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm402549>

.htm Beginning on June 26, 2014, the FDA has invited public comment on the Small Entity Compliance Guide at <http://www.regulations.gov> (using docket number FDA-2005-N-0404)

[12] Id.

[13] <http://www.celiaccentral.org/great-gluten-free-foodservice-training/>

[14] <http://www.celiaccentral.org/Courses/Pricing/1055/>

[15] <http://www.gf-cert.org/>

[16] <http://www.gf-cert.org/>

[17] <http://www.glutenfreecert.com/certification/certification-process/> ;
<http://www.glutenfreecert.com/certification/certification-costs/>

[18] <https://www.gluten.net/programs/industry-programs/gluten-free-certification-organization/faq-gluten-free-certification-organization-gfco/#CERTIFICATION>

[19] <https://www.gluten.net/programs/industry-programs/gluten-free-certification-organization/faq-gluten-free-certification-organization-gfco/#CERTIFICATION>

[20] <http://www.healthydiningfinder.com/Expert-Nutrition-Services#Gluten>

[21] <http://www.menutrinfo.com/certified-gluten-free/>; <https://www.linkedin.com/company/kitchens-with-confidence-llc>

[22] <http://www.menutrinfo.com/allergy-training/>

[23] The CSA's Recognition Seal reads: "The appearance of this Seal on packaging certifies: (1) that the manufacturer adheres to the Celiac Sprue Association (CSA) standards – free of wheat, barley, rye and common oats, their crosses and derivatives in product, processing and packaging or (2) that innovative products have been crafted to remove the gluten from the finished product. Verification testing must confirm no detectable gluten using the most appropriate analysis for the product."
(http://www.csaceliacs.org/csa_recognition_seal.jsp)

[24] http://www.csaceliacs.info/defining_the_term_glutenfree.jsp;
http://www.csaceliacs.org/csa_recognition_seal_program_requirements.jsp

[25] http://www.csaceliacs.info/defining_the_term_glutenfree.jsp

[26] <http://www.nsf.org/services/by-industry/food-safety-quality/organic-and-specialty-certifications/gluten-free>
