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Timely Topics in Gluten-Free Labeling

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Patients with the inherited autoimmune condition, celiac disease, must avoid gluten in any form to help heal damaged intestinal villi. The Food and Drug Administration's (FDA) Gluten Free (GF) label is intended to help instill trust in consumers with celiac disease and gluten-related disorders. Studies show that the vast majority of labeled GF foods meet the FDA's standard of <20 ppm gluten, but consumers remain leery of some labeled GF products, especially those displaying allergen advisory statements for wheat. Products containing malt, malt extract, and other gluten-containing ingredients continue to show up on store shelves, which may indicate that FDA enforcement of the GF labeling rule is lacking. Consumers may find a personal allergen detection tool to be an attractive option to assist in testing food for gluten content, but these also come with significant limitations.

INTRODUCTION

Celiac disease is an autoimmune condition treatable only with a strict, lifelong GF diet.[1] The FDA's GF labeling rule, enacted in 2013, set the standard for what GF means on the food label.[2] Despite research that shows that the vast majority of labeled GF products contain levels of gluten well below the FDA's standard of <20 ppm gluten, many GF consumers continue to be concerned about the safety of labeled GF foods.[3,4] These concerns may convince some that a personal allergen detection tool is necessary to assure that labeled GF food is safe. What are some of the issues surrounding GF labeling that should be addressed to help consumers feel more confident that the foods that they purchase are safe?

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Allergen Advisory Statements

Because there is little regulation behind them, allergen advisory statements such as "made in a shared facility," "made on shared equipment," or "may contain" statements cause significant skepticism amongst GF consumers.[5] Is this concern warranted? Are GF foods with allergen advisory statements for wheat inherently riskier than those without such warnings?

The 2004 Food Allergy Labeling and Consumer Protection Act (FALCPA) states that any of the eight major food allergens present as an ingredient must be listed by either their "common or usual name of the major food allergen in the list of ingredients," or "the word 'Contains', followed by the name of the food source from which the major food allergen is derived immediately after or adjacent to the list of ingredients…".[6] FALCPA

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only applies to the ingredients in the food; it does not apply to manufacturer practices.

In contrast, allergen advisory statements are voluntary on the part of the manufacturer. While the FDA does state that allergen advisory statements "should not be used as a substitute for adherence to Good Manufacturing Practices (cGMPs)" and must be "truthful and not misleading," these statements are not otherwise defined under any federal regulation.[7]

The FDA's GF labeling rule states that any unavoidable gluten in a product making a GF claim must be < 20 ppm.[2] This applies to gluten that may naturally be in the food as part of an allowed ingredient (i.e., wheat starch) or through unintentional cross-contact with wheat, barley, or rye. In other words, a product may carry a GF label claim in addition to an allergen advisory statement, provided the final product meets the standard of < 20 ppm gluten.[2] The FDA does state that the allergen advisory statement must be "truthful and not misleading" and that the "FDA evaluates labels on a case-by-case basis to determine whether a specific advisory statement included along with a GF claim would be potentially misleading to the consumer".[8]

Two recent studies examined foods with and without GF labels to determine if an allergen advisory statement predicted contamination with wheat or gluten. The first, a 2016 retrospective review of 101 foods tested for gluten content through Gluten Free Watchdog, LLC, examined the product labels of foods not specifically labeled GF, but appearing to be free of gluten based on a thorough review of the ingredients list. Of the 101 products reviewed, 87 did not include an allergen advisory statement for wheat or gluten on the packaging. Of the 87 products without a statement, 13 contained quantifiable levels of gluten at or above 5 ppm, with 4 of those being at or above 20 ppm. Of the 14 products with an allergen advisory statement, 1 contained a quantifiable level of gluten (testing at or above 20 ppm).[9]

The second study retrospectively examined the information from product packaging for 328 foods tested for gluten content through Gluten Free Watchdog, LLC that were labeled GF. Of the products reviewed, 297 did not include an allergen advisory statement for wheat or gluten on product packaging, while 31 did include a statement. Of the 297 products that did not include a statement, 39 contained quantifiable gluten at or above 5 ppm, with 12 of those testing at 20 ppm or above. Of the 31 products with an allergen advisory statement, 3 contained at or above 5 ppm gluten, including 2 that tested at or above 20 ppm.[5]

The authors from these studies concluded that "the use of allergen advisory statements (regardless of type) on foods labeled GF was not indicative that a food was out of compliance with the GF labeling rule".[5] They also concluded that "due to the current lack of federal regulations for allergen advisory statements, consumers with celiac disease and other gluten-related disorders should not make GF purchasing decisions based solely on the presence or absence of an allergen advisory statement for wheat".[5]

Still, allergen advisory statements cause significant worry, and many patients on the GF diet continue to avoid products with these statements. To help alleviate these concerns, the FDA should strongly consider taking action by regulating these statements, such as requiring additional verbiage on product packaging such as "regardless of the presence of an allergen advisory statement for wheat, this product must comply with all criteria of the GF labeling rule".[5] Consumers with questions regarding allergen advisory statements should contact the manufacturer to inquire about

Table 1. Questions to Ask Manufacturers Regarding Products Displaying Allergen Advisory Statements

- Speak to a representative who is familiar with the Allergen Control Plan.
- Are there dedicated areas, employees, and equipment that produce GF foods?
- Are there procedures for receiving and storage to keep GF foods away from gluten-containing foods?
- How is the equipment cleaned?
- Are GF foods produced on different days, or at least first (before gluten-containing foods)?

precautions taken in facilities and on equipment; examples are found in Table 1.

Facial Misbranding

In addition to the final product containing < 20 ppm gluten, a food with a GF label must not include certain prohibited ingredients under the FDA's rule.[2] Despite this, consumers have found several labeled GF foods available that contain ingredients that are not allowed. The prohibited ingredients most often found include barley malt, barley malt extract/barley malt syrup, barley malt vinegar, and wheat-based soy sauce.[10]

Tricia Thompson, MS, RD, LD, founder of the independent gluten testing organization, Gluten Free Watchdog, LLC, and Kaki Schmidt, Esq. coined the phrase "facial misbranding" to describe these products.[11] A product that is facially misbranded displays a GF label claim, but the ingredient list notes a prohibited ingredient under the FDA's GF labeling rule, such as malt extract or malt syrup.

Why the confusion over what may or may not be included in food labeled GF? Some manufacturers may believe that the only thing that is required for a GF claim is that the final product contains <20 ppm gluten, overlooking the fact that certain ingredients are not permitted in foods labeled GF in the United States. Lax enforcement from the FDA of the GF labeling rule also plays a role. The FDA states,

Table 2. Reporting a Product to the U.S. Food and Drug Administration (FDA)[25]

A. Product name

B. Gluten-free claim

C. "Contains" statement

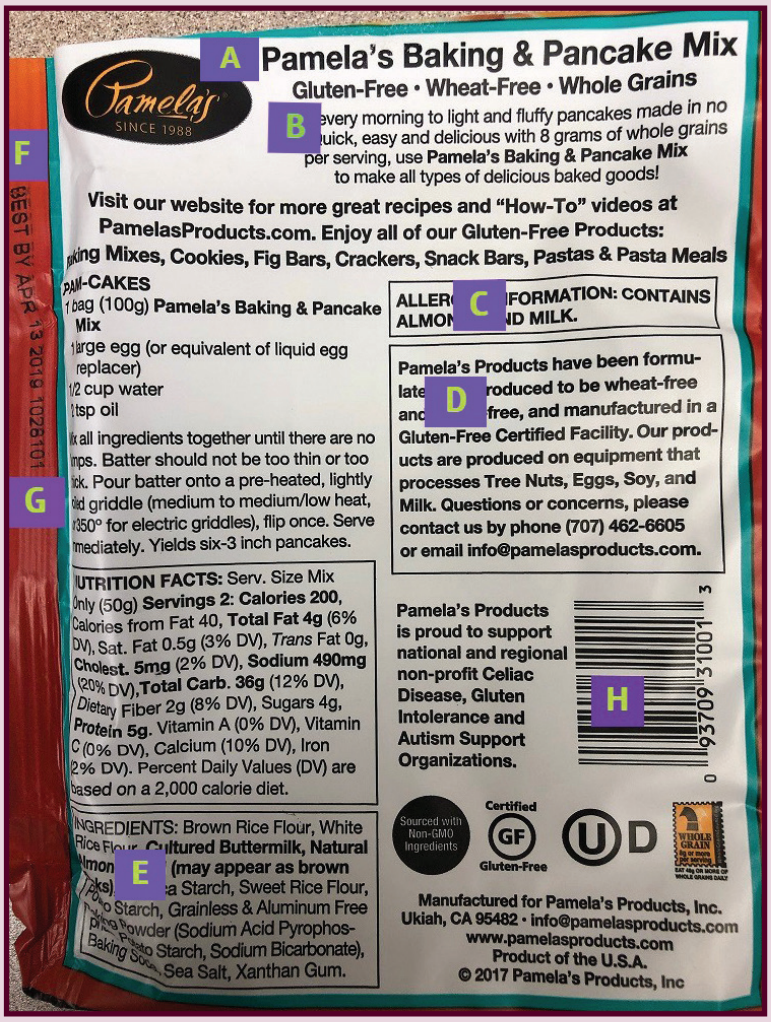
D. Wording about gluten-free status printed after the "Contains" statement

E. Ingredients list

F. Sell-by/use by/expiration date.

G. The lot number

H. UPC code



**Example shown is for demonstration purposes only; this product is not in violation of GF labeling laws.*

Table 3. Reporting a Product to the United States Department of Agriculture (USDA)[26]

A. Brand name

B. Product Name

C. Manufacturer

D. Size/Package Type

E. Date/can and package code (not UPC)

F. Establishment number (EST) (this is usually found in the mark of inspection but may also be ink jetted onto the packaging) It is crucial to provide this number when reporting a product.

G. GF claim

H. Ingredients list

**Example shown is for demonstration purposes only; this product is not in violation of GF labeling laws.*

"The agency will use the full range of its routine post-market monitoring activities to enforce the final rule on GF food labeling…" and "that these activities include...food label reviews".[8] However, between the beginning of 2016 and late 2018, only eight recalls had been issued for GF foods due to facial misbranding.[12]

Thompson and Schmidt filed a citizen petition to the FDA in August 2017 detailing numerous products that remained on store shelves that contained prohibited ingredients.[13] The request also asked for the establishment of protocols that would improve surveillance, investigation, and enforcement of misbranded products. Progress is being made on this issue, however. In 2018, the FDA met with Thompson and representatives from all four national celiac organizations to discuss GF labeling issues.[14] While this issue remains in active discussion, consumers are still strongly encouraged to report potentially misbranded GF foods to the FDA and USDA. Details of this process are found in Table 2 and Table 3, and on page 36.

Consumer Testing Devices

Up until a couple of years ago, testing food for gluten content was reserved for the laboratory, utilizing methods such as the scientifically validated R5 ELISA Mendez Method.[15,16] The proper testing protocol requires thorough homogenization of a

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representative sample of the food to be tested (usually through grinding), which is then added to a cocktail solution. It is generally recommended to test at least two extractions to help ensure that the sample has been sufficiently homogenized (i.e., any gluten present has been evenly distributed within the sample). ELISA testing, while considered accurate and reliable, is not something that consumers can perform at their favorite restaurant or a family picnic.

The advent of portable gluten and allergen sensors now provides GF consumers the ability to conduct "point of service" testing of foods,

Table 4. Steps to Getting a Safe GF Restaurant Meal

Plan Ahead

- Research restaurant options online or utilizing a smartphone app.
- The availability of a GF menu does not guarantee safety but can be a starting point for asking questions about specific items.
- Consider calling ahead to ask questions about the menu; a restaurant that employs a chef may be more able to accommodate special dietary requests.
- Try not to dine at the busiest time of day.

When Ordering

- Identify yourself to the server or manager. "I have celiac disease and cannot have any foods that contain wheat, rye, barley, or oats. I have some questions about the menu."
- Consider asking for the manager or chef, if available. Verify what you should be looking for in terms of how GF meals are served (i.e., a different color plate or rim around the plate).

Ask Detailed Questions About Ingredients (not an exhaustive list).

- Are sauces thickened with flour?
- Do marinades contain soy sauce or malt vinegar?
- Do soup bases or broth contain wheat?
- Is flour added to scrambled eggs?
- Do salad dressings contain malt vinegar or soy sauce?
- Are there coatings or breading on meats, poultry, or fish?
- Are bean dishes thickened with flour?
- Are seasoning mixes added to meat, poultry, fish, potato, or rice dishes?

Ask Detailed Questions About Preparation Methods to Prevent Cross Contact (not an exhaustive list).

- Are French fries prepared in a dedicated or shared fryer?
- Is GF pasta prepared in the same water as regular pasta?
- Is there a dedicated area on the grill for cooking meat, poultry, or fish?
- Do you use separate toppings to prepare GF pizza?
- Do you use separate utensils to prepare and serve GF food?

When the Meal is Served

- Confirm with the server that the GF meal served is the one that was ordered.

After the Meal

- Thank your server, manager, and chef. Tip well. Give the restaurant repeat business, or post a review on a GF app or website.

particularly in restaurants where cross-contact with gluten is a constant concern. These products are marketed to consumers as a way to feel more secure about eating away from home or double-checking the GF status of packaged foods.[17] Do these detectors provide an accurate representation of whether a food is GF, and do they increase the likelihood that consumers can avoid gluten when eating away from home?

One such sensor, Nima, is an example of a lateral flow device.[18] A lateral flow device is a dipstick test, similar to a home pregnancy test. It can only qualitatively determine whether gluten is present or not versus quantifying the amount of gluten present in food. The Nima Sensor requires users to insert a "pea-sized" amount of the food to be tested into a capsule, which is then inserted into the handheld device. A few minutes later, the device's digital display will produce either a "smile" (gluten found or gluten detected at <20 ppm) or just "gluten found".[19]

There are significant limitations to this type of testing. The first, and probably most notable is sampling. While R5 ELISA testing is conducted on a representative well-homogenized sample, a small amount from a non-homogenized sample is not representative of the safety of the meal as a whole.[20] Another limitation of the Nima is that it is not able to detect fermented or hydrolyzed gluten. If a dish contained soy sauce or beer, for example, the Nima would not detect gluten from those ingredients.[20]

In addition, a reviewer of this article with celiac disease identified other potential limitations, including cost; the sensor retails for $289 and capsules required for testing are approximately $5 each. The sensor also takes 3 minutes to display results for each piece of food tested, which could result in a significant delay in eating if several items were tested on a plate. And while the device is fairly small, remembering to take the device to every meal away from home could be cumbersome.

There has also been some inconsistency on the sensitivity of the Nima Sensor. According to data published on the Nima website, when a food contains <2 ppm, the Nima will detect "gluten found" 8% of the time.[21] A third party evaluation study found that the Nima reported "gluten found" 27% of the time (21 out of 78 samples) when the gluten level is 5 ppm, and about 56% of the time when gluten is 10 ppm (44 out of 78 samples). In the same study, the Nima did not detect gluten in any sample of one type of pasta at 20 ppm; it was not until the pasta was at 30 ppm gluten that the sensor detected gluten.[20] Because the device cannot provide consumers with an exact amount of gluten, "gluten found" may indicate gluten concentrations anywhere from < 2 ppm to 30 ppm or more.

It is important to note that there is no FDA approval or testing required for sensors such as the Nima before they are released to the marketplace.[22] The Canadian Celiac Association's published position statement from March 2018 did not recommend the Nima Sensor for people with celiac disease or non-celiac gluten sensitivity.[23] Other experts advise against the use of personal allergen/gluten testers, yet consumers are using them.[22,24] If a consumer chooses to use one, it is imperative to understand their limitations. Consumers should be encouraged to continue to ask questions about ingredients and preparation methods in restaurants to help ensure they receive a safe meal. Examples of questions that should be asked in restaurants are found in Table 4.

Should Consumers Trust the GF Label?

Despite the issues discussed in this article, GF consumers should rest assured that most of the labeled GF foods that they purchase are safe. A 2012 study of labeled GF foods in Europe found that 99.5% of samples tested were found to contain gluten at <20 ppm, while 94% contained <5 ppm gluten, the lowest level of quantification measurable utilizing the R5 ELISA Mendez Method.[3] which is consistent with findings from a 2014 U.S. study.[4] In addition to asking food manufacturers about facility practices to control for cross-contact with gluten, and reviewing ingredient lists of labeled GF foods, there are other reasonable steps that consumers can take to help protect themselves. For example, purchasing inherently GF grains and lentils specifically labeled GF can reduce the risk of cross contact. Enjoy more naturally GF foods that are at low risk of contamination with gluten such as fruits, vegetables, and plain meats. And while it's not necessary to limit to only those products, consumers can look for third party certifications of GF status.

What Should Consumers Report?

Any product displaying a GF label claim with an ingredient that is prohibited under the GF labeling rule. Consumers should contact an FDA consumer complaint coordinator using the list at: **https://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/**

What Should Consumers Not Report?

A product displaying a GF label claim that also has an allergen advisory statement (i.e., made in a shared facility/equipment or may contain). These are permitted on labeled GF foods provided that the final product is < 20 ppm gluten.

Does USDA Have a GF Labeling Rule?

The USDA does not have a GF labeling rule but does state that manufacturers who include a GF claim on product packaging must comply with the FDA rule.

What Foods Does USDA Regulate?

- Meats, poultry, and dried, frozen, or liquid egg products, made with our without added ingredients.
- Mixed ingredient foods that contain greater than 3% raw meat, 2% or more cooked meat or poultry.
  - Note the name and location of the store.
  - Note the date that you purchased (or spotted) the product.
  - Contact the USDA 1-888-674-6854
- From The Labeling and Program Delivery Staff, USDA, Food Safety and Inspection Program (FSIS): "FSIS has a system in place for consumers to report complaints, including labeling concerns, about products under FSIS' jurisdiction. This centralized reporting system collects all of the relevant information and directs the complaint to the appropriate staff within FSIS".[26]
  - Website: https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/report-a-problem-with-food/report-a-problem-with-food
  - The complaint may be initiated by phone or electronically.
  - Call the toll-free (1-888-674-6854) or report the complaint online https://ccms.fsis.usda.gov/ECCF/ ■

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