



When foods contain both a gluten-free claim and an allergen advisory statement for wheat: should consumers be concerned?

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On 05 August 2013, the U.S. Food and Drug Administration's (FDA) gluten-free labeling rule took effect [1]. Under this rule, manufacturers of foods regulated by the FDA who voluntarily choose to include a gluten-free claim on product packaging must make sure their products are in compliance. One of the criteria for labeling a food gluten-free is that it contains a level of gluten below 20 parts per million (p.p.m.). This level applies to gluten that may be in a product naturally as part of an allowed ingredient, such as wheat starch or unintentionally through cross-contact with wheat, barley, or rye.

Under the gluten-free labeling rule, food labels may include both a gluten-free claim and an allergen advisory statement for wheat. The FDA addresses this apparent contradiction in an online guidance document [2]:

“The final rule does not prohibit the inclusion of an advisory label statement, such as “made in a facility that also processes wheat,” on foods labeled gluten-free, provided that the statement is truthful and not misleading. FDA evaluates food labels on a case-by-case basis to determine whether a specific advisory statement included along with a gluten-free claim would be potentially misleading to the consumer. However, any food whose label bears a gluten-free claim, regardless of whether it also has an advisory statement, must meet all the requirements of the final rule.”

Regardless, consumers with celiac disease and other gluten-related disorders are often wary of products labeled gluten-free that also include an allergen advisory statement for wheat or gluten on product packaging.

In the U.S. allergen advisory statements are voluntary and are not currently defined by any federal regulations [3]. The FDA does state in various online documents that such statements, “should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs)” and “must be truthful and not misleading” [3]. Under the recent Food Safety and Modernization Act, which does not appear to directly address allergen advisory statements, facilities covered by this act must have a written food safety plan that includes procedures to “control allergen cross-contact” [4, 5].

Allergen advisory statements are not the same as allergen declarations required under the Food Allergen Labeling and Consumer Protection Act (FALCPA) [6]. Under this act, if an ingredient in a food is or contains any of eight major allergens, the allergen must be named on the label in plain English in either the ingredients list (e.g., starch [wheat]) or a separate Contains statement (e.g., Contains wheat). FALCPA applies to ingredients only while allergen advisory statements apply to processing practices that may result in cross-contact with allergens.

There is very little published data on the gluten levels of products labeled gluten-free that also contain an allergen advisory statement for wheat or gluten on product packaging. In a study published in this journal, it was reported that 20 snack bars labeled gluten-free were tested for gluten and product packaging was reviewed for an allergen advisory statement [7]. All bars tested below 20 p.p.m. of gluten, yet 5 bars contained an allergen advisory statement for wheat on product packaging. In another study, also published in this journal, 8/158 (5%) foods labeled gluten-free and tested for gluten contained at least 20 p.p.m. [8]. However, none of these 8 products contained an allergen advisory statement for wheat or gluten on product packaging. The purpose of the present study is to build upon these

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Table 1 Summary of findings of foods labeled gluten-free

Testing results	Number of products (<i>n</i> = 328)	Contained an allergen advisory statement for wheat/gluten (<i>n</i> = 31)	Did not contain an allergen advisory statement for wheat/gluten (<i>n</i> = 297)
<20 p.p.m. of gluten	314	29 (9%)	285 (91%)
≥20 p.p.m. of gluten	14	2 (14%)	12 (86%)
<i>p.p.m.</i> parts per million			

earlier studies by reviewing the labeling claims and gluten testing data of hundreds of foods labeled gluten-free.

Allergen advisory statement label review

Labeling information compiled for 328 gluten-free products tested for gluten content was retrospectively reviewed for an allergen advisory statement for wheat or gluten. Products reviewed for this analysis were labeled gluten-free at the time of testing. The presence (and type) of precautionary allergen labeling was recorded after the product was purchased. Only precautionary labeling information included on product packaging was used. Allergen advisory statements from manufacturer websites were not considered.

Products were tested through the gluten test reporting service Gluten Free Watchdog, LLC in Manchester, MA, USA. All commercially available products tested by Gluten Free Watchdog and labeled gluten-free at the time of this analysis were included in this review. Products were chosen for gluten testing through this service based either on convenience (readily available online or in grocery stores in Massachusetts) or because a request for testing was received from a member of the Gluten Free Watchdog community.

Testing for gluten was done through Bia Diagnostics, LLC in Colchester, VT, USA. Each product sample was tested in duplicate using the Ridascreen Gliadin sandwich R5 enzyme-linked immunosorbent assay ELISA Mendez method (Ridascreen Gliadin R7001) and extracted with the cocktail solution (Art. No. R7006—official Mendez method) following the kit manufacturer instructions (R-biopharm, Darmstadt, Germany) [9]. If there was the possibility that the food might contain gluten protein fragments due to the use of certain ingredients (e.g., wheat starch), it also was tested using the competitive R5 ELISA (Ridascreen Gliadin R7021) and extracted with ethanol following the kit manufacturer instructions.

Findings and lessons learned

As can be seen in Table 1, 14/328 (4%) labeled gluten-free products contained a level of gluten of at least 20 p.p.m. Of these products, 12/14 (86%) did not include an allergen advisory statement for wheat or gluten on product packaging. The 14 products that contained a level of gluten of at least 20 p.p.m. included two beverages, one spice, and 11 grain-based foods. Of the grain-based foods, 5/11 (45%) were oat products.

As is illustrated in Table 2, 31/328 (9%) foods tested for gluten included an allergen advisory statement for wheat or gluten on product packaging. Three of these 31 (10%) products contained quantifiable gluten of at least 5 p.p.m.

Table 2 Products that contained an allergen advisory statement and their p.p.m. gluten level ($n = 31/328$)

Product type	Gluten level	Allergen advisory statement
Chocolate bar	<5	Manufactured on equipment that also processes wheat
Cookies	<5	Manufactured in a facility that also makes products containing wheat
Cookies	<5	Produced in a facility that also handles wheat
Cookies	<5	May contain traces of wheat
Brownie	<5	Manufactured in the same plant as wheat
Cookies	<5	Made in a facility that processes wheat
Crackers	<5	Produced in a facility that also makes products containing wheat
Crackers	<5	Made in a kitchen that uses wheat
Crackers	<5	Manufactured in a facility that also produces products that contain wheat
Entree	<5	Produced in a facility that also processes wheat
Hot cereal	<5	Packaged in a facility that also handles wheat
Grains	<5	Manufactured in a facility that processes wheat
Grains/oats	72 to >84	Manufactured in a facility that also processes wheat
Mix	<5	Manufactured in a facility that processes wheat
Nuts and seeds	<5	Product is manufactured on equipment shared with wheat products
Pasta	<5	Processed in a facility that uses wheat
Pasta	<5	Processed in a facility that uses wheat
Pasta	<5	Processed in a facility that uses wheat
Ready-to-eat cereal	<5	Manufactured in a facility that also processes wheat
Ready-to-eat cereal/oats	<5–26 ^a	Manufactured in a facility that handles wheat
Snack bar	<5	Processes other foods that may contain wheat
Snack bar	12–15	Produced in a facility that also processes wheat
Snack bar	<5	May also contain wheat
Snack bar	<5	This product was produced in a facility that may also process ingredients containing wheat
Snack bar	<5	Produced on equipment that also processes wheat
Snack bar	<5	Manufactured in a facility that processes wheat
Snack food	<5	Made in a facility that may use wheat
Snack food	<5	Manufactured on equipment that also processes wheat
Soup	<5	This product is made in a facility that also processes foods containing wheat
Soup	<5	This product is made in a facility that processes foods containing wheat
Soup	<5	Facility not dedicated gluten free

^aTwo separate samples tested. Extractions from first sample: both <5 p.p.m.; Extractions from second sample: 16 p.p.m., 26 p.p.m

Allergen advisory statements on product packaging included 25 precautionary statements for a shared facility, plant, or kitchen, 4 precautionary statements for shared equipment, and 2 precautionary statements that read, “may contain traces of wheat” and “may contain wheat.” The 3 products with quantifiable gluten of at least 5 p.p.m. that included an allergen advisory statement for wheat or gluten used similar statements on product packaging. These statements read manufactured/produced in a facility that processes/handles wheat.

While the vast majority of gluten-free products tested in this analysis were in compliance with the gluten-free

labeling rule and contained a level of gluten below 20 p.p.m., a small minority were not in compliance. The presence or absence of an allergen advisory statement for wheat or gluten on product packaging was not a useful predictor of this compliance.

Limitations

This retrospective database review involved 328 foods labeled gluten-free chosen for testing without regard to the absence or presence (or type) of allergen advisory statement

on product packaging. Studies specifically designed to assess labeled gluten-free foods containing allergen advisory statements for wheat or gluten would be useful. Studies specifically designed to compare the gluten levels of products with different types of allergen advisory statements (e.g., processed in the same facility, processed on the same lines, and may contain) also would be helpful.

Consumer interpretation of different types of allergen advisory statements

On the basis of an informal questionnaire posted on social media, people avoiding gluten may place different levels of importance on allergen advisory statements depending upon the wording. The following two questions were asked on Twitter to followers of Gluten Free Watchdog: (1) What is more concerning on a labeled gluten-free food: processed in a shared facility with wheat or processed on shared equipment with wheat, (2) How concerned are you about “may contain wheat” statements on labeled gluten-free foods? Based on the responses, a “produced in the same facility” statement does not cause as much concern as a “produced on the same equipment” statement. A “may contain” or “may contain traces of” statement causes the most concern.

Even when products are labeled gluten-free, the presence of a precautionary statement for wheat, especially the use of wording such as “same equipment” or “may contain”, may cause some consumers to avoid the product. Representative responses from Twitter corrected for spelling and grammar include the following:

- Shared equipment is way more concerning! I don't buy things made on shared equipment with wheat! Shared facilities may or may not be safe, depends on the company.
- Will not buy a product made on shared equipment. I will consider 'in the same facility' but even then I won't buy that 2/3 of the time.
- Shared equipment is scarier, though supposedly they clean the machinery between runs. Still, nope! If it “may contain” wheat, I don't eat!
- I eat same facility but not same equipment. I don't eat may contain wheat.
- Shared equipment is definitely more concerning than shared facility, although if I can avoid both then I will!
- Won't buy any of it. Shared facility, shared equipment, may contain wheat. Basically “this might be gluten free. But probably not.”
- More concerned about shared equipment than facility. Might touch same equipment is more concerning than simply being in the same building. I am very concerned

about products labeled GF with a “may contain wheat” statement and puzzled by certified products like this.

Current recommendations for foods labeled gluten-free containing precautionary statements

Gluten-free consumers are advised to trust the gluten-free claim on product packaging. Under the FDA's gluten-free labeling rule, food labeled as gluten-free must contain <20 p.p.m. of gluten regardless of whether gluten is present intentionally due to an allowed ingredient (e.g., wheat starch) or unintentionally due to cross-contact with wheat, barley, or rye [1].

One issue that may be causing mistrust among gluten-free consumers when products contain both a gluten-free claim and a precautionary statement for wheat is the lack of required testing for foods labeled gluten-free. In the US, while foods must contain <20 p.p.m. of gluten to be labeled gluten-free, testing is not included in the FDA's codified rule. The agency addresses the lack of a testing requirement in an online guidance document [2]:

“Are manufacturers required to test for gluten to make a gluten-free claim on their food labels?

No. The final rule does not specifically require manufacturers to test for the presence of gluten in their starting ingredients or finished foods labeled gluten-free. However, manufacturers are responsible for ensuring that foods bearing a gluten-free claim meet the requirements of the final rule. Among other requirements, this means that any unavoidable gluten present in a food labeled gluten-free is less than 20 ppm. Manufacturers may choose to use effective quality control tools to ensure that any foods they label gluten-free do not contain 20 ppm or more gluten, such as:

conducting in-house gluten testing of starting ingredients or finished foods,
employing a third-party laboratory to conduct in-house gluten testing,
requesting certificates of gluten analysis from ingredient suppliers, or
participating in a third-party gluten-free certification program.”

Requiring manufacturers who choose to place a gluten-free claim on product packaging to test for gluten may increase consumer confidence in products that are more prone to cross-contact with wheat, barley, and rye (e.g.,

grain products such as oats), as well as those products that include precautionary statements for wheat on product packaging.

Additional future needs

Increased education is needed to advise consumers that a gluten-free claim applies to gluten that may be in a product due to ingredients and cross-contact. Under the gluten-free labeling rule, a gluten-free claim on product packaging means the food must comply with all criteria of the rule, including containing <20 p.p.m. of gluten. This is true regardless of the presence or absence of an allergen advisory statement for wheat [2].

Regardless, a “may contain wheat” statement on foods labeled gluten-free understandably causes angst among some persons with celiac disease and other gluten-related disorders. To help avoid consumer confusion, the FDA should consider requiring additional verbiage on product packaging when both a gluten-free claim and allergen advisory statement for wheat are present. This statement could be as simple as, “Regardless of the presence of an allergen advisory statement for wheat, this product must comply with all criteria of the gluten-free labeling rule.” This is similar to what is currently done on product packaging when wheat is included in the ingredients list or Contains statement as required under FALCPA and the product is also labeled gluten-free. Under FALCPA, the word “wheat” must be followed by an asterisk that leads to another asterisk and the statement, “The wheat has been processed to allow this food to meet the Food and Drug Administration requirements for gluten-free foods” [1, 6].

Summary

On the basis of this retrospective data analysis, the use of allergen advisory statements (regardless of type) on foods labeled gluten-free was not indicative that a food was out of compliance with the gluten-free labeling rule. Due to the current lack of federal regulations for allergen advisory statements, consumers with celiac disease and other gluten-related disorders should not make gluten-free purchasing decisions based solely on the presence or absence of an allergen advisory statement for wheat.

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Compliance with ethical standards

Conflict of interest Tricia Thompson is the owner/founder of Gluten Free Watchdog, LLC. The remaining authors declare that they have no conflict of interest.

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