

## PERSPECTIVE

# A comparison of gluten levels in labeled gluten-free and certified gluten-free foods sold in the United States

T Thompson<sup>1</sup> and S Simpson<sup>2</sup>

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On 5 August 2013, the United States Food and Drug Administration (FDA) published the long-awaited rule for gluten-free labeling of food.<sup>1</sup> This rule went into effect on 4 September 2013. Manufacturers of packaged food products, including imported foods that fall under the labeling jurisdiction of FDA who voluntarily choose to label their foods gluten-free, must be in compliance by 5 August 2014.

Under the FDA's gluten-free rule, foods making a 'gluten-free' claim (or using the synonyms 'no gluten', 'free of gluten' and 'without gluten') on product packaging must be either (1) naturally gluten-free (for example, bag of raw carrots) or (2) comply with all of the following criteria: not contain an ingredient that is a gluten-containing grain (for example, wheat); not contain an ingredient derived from a gluten-containing grain that has not been processed to remove gluten (for example, wheat flour); not contain an ingredient derived from a gluten-containing grain that has been processed to remove gluten (for example, wheat starch) if use of that ingredient causes the food to contain  $\geq 20$  parts per million (p.p.m.) of gluten, and the presence of any gluten in a food must be  $< 20$  p.p.m. gluten.<sup>1</sup>

Although the FDA rule requires foods labeled gluten-free to contain  $< 20$  p.p.m. gluten, there is no stipulation in the rule that manufacturers making a gluten-free claim must test foods for gluten content.<sup>2</sup> The lack of an FDA testing requirement may cause some consumers with gluten-related disorders to wonder whether the gluten-free foods they buy are in compliance with the labeling rule. As a result, US consumers may choose to buy only those products that have been specially certified as gluten-free by a third-party certification organization. There may be an underlying assumption that certified products have a greater likelihood of being in compliance with the gluten-free labeling rule.

There is very little published data comparing the gluten level of labeled but not certified gluten-free foods and foods specially certified as gluten-free.<sup>3</sup> In a published report on the gluten content of foods labeled gluten-free (regardless of certification), it was noted that one of the four gluten-free products testing  $\geq 20$  p.p.m. of gluten was certified gluten-free.<sup>3</sup> The purpose of the present evaluation is to help build upon this finding by closely assessing the gluten levels of both categories of foods.

## GLUTEN EVALUATION OF FOODS

Between April 2011 and April 2014 foods labeled gluten-free were purchased from retail establishments in the United States, including grocery stores and online merchants. The only

requirement for purchase was that the product was labeled gluten-free. Products were chosen based either on convenience (readily available online or in grocery stores in Massachusetts) or because a request for testing was received through the gluten test reporting service Gluten Free Watchdog in Manchester, MA, USA. Whether or not a product was certified was not a criterion for testing. Products tested included baking ingredients, beverages, bread products, chili, condiments, cookies, crackers, entrees, flour, grains, gravy, hot cereal, mixes, nuts and seeds, pasta, ready-to-eat cereal, snack bars, snack food, soup, spices, supplements and tortillas. A total of 158 products were tested, including 46 products certified as gluten-free.

Products were sent unopened to the third-party allergen testing facility Bia Diagnostics in Burlington, 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's directions (R-biopharm, Darmstadt, Germany).<sup>4</sup> If the food was suspected of containing gluten protein fragments owing to the use of certain fermented or hydrolyzed ingredients, it also was tested using the competitive R5 ELISA (Ridascreen Gliadin R7021) and extracted with ethanol following the kit manufacturer's directions.<sup>5</sup> Gluten protein fragments can not be adequately detected using a sandwich ELISA, so a competitive ELISA must be used.<sup>6,7</sup> Both testing methods have been previously described.<sup>6,7</sup> The lower limit of quantification for the sandwich R5 ELISA is 5 p.p.m. gluten. The lower limit of quantification for the competitive R5 ELISA is 10 p.p.m. gluten.

## LESSONS LEARNED

As can be seen from Table 1, approximately 95% of labeled gluten-free free food products tested  $< 20$  p.p.m. gluten, with approximately 87% testing  $< 5$  p.p.m. gluten. There are some foods both certified and not certified that tested  $\geq 20$  p.p.m. gluten. As can be seen from the Supplementary Table available online, these foods include a wide range of products, namely a hot beverage, bread product, bread crumbs, crisp bread, cookie, hot cereal, spice and tortilla. Approximately 5% of foods labeled gluten-free but not certified tested  $\geq 20$  p.p.m. gluten. Approximately 4% of foods certified gluten-free tested  $\geq 20$  p.p.m. gluten. There also were some certified gluten-free products that tested  $< 20$  p.p.m. gluten but tested above the gluten levels set by the certifying organization. The Supplementary Table available online provides detailed results of all the products tested.

There are many reasons why a labeled gluten-free food may test at or above 20 p.p.m. gluten, including manufacturer's testing protocols. Some manufacturers may not be testing their products. If they are testing, they may not be testing every batch/lot of

<sup>1</sup>Gluten Free Watchdog, Manchester, MA, USA and <sup>2</sup>Celiac Disease Center at Columbia University, Harkness Pavilion, New York, NY, USA. Correspondence: T Thompson, Gluten Free Watchdog, 348 Summer Street, Manchester, MA 01944, USA.

E-mail: tricia\_s\_thompson@hotmail.com

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**Table 1.** Summary findings of the gluten content of foods labeled gluten-free and foods certified gluten-free<sup>a</sup>

Category	< 5 p.p.m.	5 to ≤ 10 p.p.m.	> 10 to < 20 p.p.m.	≥ 20 p.p.m.
All food n = 158	137 (86.7%)	6 (3.8%)	7 (4.4%)	8 (5.1%)
Food labeled gluten-free but not certified n = 112 <sup>b</sup>	96 (85.7%)	5 (4.5%)	5 (4.5%)	6 (5.4%)
Food certified gluten-free by any organization n = 46 <sup>b</sup>	41 (89.1%)	1 (2.2%)	2 (4.3%)	2 (4.3%)

<sup>a</sup>Products were categorized by gluten level based on the highest extraction test result. <sup>b</sup>Percentage values do not add up to 100% due to rounding off.

product and/or they may be testing in-house with an assay that is not fully validated.

### LIMITATIONS

The present evaluation includes the assessment of a relatively small number of labeled gluten-free foods. There is absolutely no way of knowing whether the findings of this assessment are representative of the entire gluten-free market available in the United States. Thousands of foods are labeled gluten-free, and this number will likely continue to grow. Packaged Facts estimates that by the year 2017 the sale of gluten-free foods and beverages in the United States will be > 6.6 billion.<sup>8</sup> The FDA allows any food, including bottled water and bags of raw carrots, to be labeled gluten-free as long as the labeling criteria are met. The FDA has stated in their Regulatory Impact Analysis of the gluten-free labeling rule that, 'We estimate that after products with a 'gluten-free' label are tested and their ingredient lists examined, 5% of these foods will be found to need relabeling to comply with this final rule. This includes the 4.9% of foods with 20 p.p.m. or more gluten and 0.1% with ingredients that do not satisfy the ingredient requirements in this final rule. This estimate of 0.1% is based on a search of ingredients of foods with a 'gluten-free' claim in the Food Essentials database'.<sup>9</sup> The numbers that the FDA is providing (that 5% of products do not meet the criteria of the gluten-free labeling rule) is in keeping with the overall findings of the current analysis.

### CERTIFICATION ORGANIZATIONS

The three main organizations certifying foods as gluten-free that are sold in the United States are the Gluten-Free Certification Organization (GFCO), the Celiac Support Association (CSA), and the Gluten-Free Certification Program (GFCP). All of the certification organizations appear to be in compliance with the FDA's gluten-free labeling rule based on the information provided on the respective organization's websites.<sup>10-12</sup> All three programs require foods to be tested and meet threshold levels of gluten that are lower than the FDA threshold of < 20 p.p.m. gluten. One criterion for qualifying for certification through CSA is that products must test < 5 p.p.m. gluten. Products certified through GFCP must test < 10 p.p.m. gluten, and products certified through GFCO must test no higher than 10 p.p.m. gluten.

The gluten-free certification organizations were initiated to provide consumer confidence when there was no US government definition of gluten-free. Both GFCO and CSA have been certifying foods, both domestic and imported, for a number of years.<sup>10,11</sup> GFCP is a relatively new certification program in the United States. It is owned and operated by the Allergen Control Group in Canada

and endorsed by the Canadian Celiac Association and the National Foundation for Celiac Awareness in the United States. Based on 2013 data, GFCO certifies approximately 26% of the gluten-free product market<sup>10</sup> (Interestingly, 27% of the products tested in this assessment were certified by GFCO). To the best of the authors' knowledge, similar data are not publicly available for the other two organizations.

The certification organizations can have a role in consumer confidence. Some consumers rely on certification symbols on food packaging to make sure the products they buy truly are gluten-free. There also may be some consumers who prefer to eat labeled gluten-free foods that test < 5 p.p.m. or < 10 p.p.m. gluten. They may choose products accordingly from the various certification organizations. The FDA states in an online guidance document that, 'Manufacturers may include the logo of a gluten-free certification program on their food labels, provided that its use is truthful and not misleading'.<sup>2</sup>

### TRUSTING THE GLUTEN-FREE LABEL

Consumers with gluten-related disorders should be able to trust the gluten-free label. Findings from this evaluation indicate that overall the gluten-free label in the United States is trustworthy 95% of the time. It is hoped that this percentage will increase after 5 August 2014 when manufacturers are expected to be in compliance with the gluten-free labeling rule. That said, if dietitians and physicians suspect a patient is inadvertently ingesting gluten, it is important to consider all food, including labeled and certified gluten-free foods, as a source of potential gluten contamination. If practitioners and/or consumers are concerned about the integrity of a gluten-free claim, there are steps they can take to increase their confidence in the product, including reading the ingredients list and contacting manufacturers to ask about the gluten-testing protocols.

### READING THE INGREDIENTS LIST

Some consumers may choose to read the ingredients list even though a product is labeled gluten-free. Among the ingredients consumers should look for include malt, malt extract and malt syrup. These ingredients are made from barley unless another source is named, such as corn malt.<sup>13,14</sup> There are several manufacturers, especially those who make chip and energy bars, who are wrongly including these ingredients in labeled gluten-free foods.<sup>15-18</sup> Over the years this has happened with both labeled gluten-free and certified gluten-free products. Some manufacturers mistakenly believe that the only criterion for labeling a food gluten-free is that it tests < 20 p.p.m. gluten. However, this is not what the FDA stipulates in the gluten-free labeling rule.<sup>1</sup> Certain ingredients can not be included in foods labeled gluten-free and sold in the United States. Whether malt ingredients can be included in labeled gluten-free foods was recently clarified by FDA.<sup>19,20</sup> During a webinar an FDA staff person stated, 'Malt extract and malt syrup are ingredients derived from gluten containing grains and containing gluten therefore we would consider them as ingredients not processed to remove gluten and they would not be permitted in foods bearing the claim gluten-free'.<sup>19,20</sup>

Consumers also should be mindful that certain ingredients containing the words 'wheat', 'barley' or 'rye' in their name are allowed in gluten-free foods as long as the final food product contains < 20 p.p.m. gluten. These ingredients include wheat starch and ingredients that may be made from wheat starch, such as 'glucose syrup (wheat)'. To help avoid confusion, the FDA has stipulated that when a food is labeled gluten-free and the word 'wheat' is in the ingredients list or Contains statement (as mandated under the food Allergen Labeling and Consumer Protection Act), it 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'.<sup>1,21</sup> In addition, the grasses of wheat, barley and rye are also allowed in foods labeled gluten-free provided the final Food product contains < 20 p.p.m. gluten.<sup>22</sup> If the word 'barley' or 'rye' is included in an ingredient name, additional verbiage is not required to be included on the label. This is because barley and rye are not included among the allergens that must be named in the ingredients list under FALCPA.<sup>21</sup>

In addition, consumers should know that oats are an allowed grain in labeled gluten-free foods. When oats are included in a single-ingredient product (for example, rolled oats), they do not have to be certified. When oats are included in a multi-ingredient product, they do not have to be either certified or gluten-free. However, as with all labeled gluten-free foods, the final product has to contain < 20 p.p.m. gluten.

### CONTACTING THE MANUFACTURING

Consumers can contact manufacturers to ask whether they test their food for gluten, what test they use and what steps they take to ensure that foods making gluten-free claims contain < 20 p.p.m. gluten. The FDA has suggested several quality-control measures manufacturers can put in place to help ensure products labeled gluten-free contain < 20 p.p.m. gluten, including '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'.<sup>2</sup> Although the FDA does not require manufacturers to test food for gluten, the Agency has stated in a guidance document the two testing methods they will use in tandem when necessary to determine compliance with the gluten-free labeling rule—the R5 ELISA Mendez Method and the Morinaga Wheat Protein ELISA.<sup>2</sup> The R5 ELISA Mendez Method is widely considered to be the best available assay for quantifying gluten.

### PRODUCT COMPLAINTS

If a consumer has a complaint about a gluten-free product (regardless of certification status) because they believe it made them sick, they should be encouraged to contact the Center for Food Safety and Applied Nutrition's Adverse Event Reporting System. The phone number is 240-402-2405. If a consumer comes across a food they believe may be wrongly labeled gluten-free, they should contact a Consumer Complaint Coordinator in their area. A listing is available at <http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm>.

### SUMMARY

Most of the products tested in this assessment contained < 20 p.p.m. gluten. Most of the certified products also tested at or below the more stringent gluten levels of the certifying organizations. However, there remains room for improvement as 100% of products labeled gluten-free should test < 20 p.p.m. gluten. If a product is voluntarily labeled gluten-free, it should have a gluten level < 20 p.p.m. If a product is voluntarily certified gluten-free, it should have a gluten level below the level set by the certifying organization. It is hoped that better oversight on the part of manufacturers of gluten-free foods will cause all foods voluntarily labeled gluten-free to be in complete compliance with the gluten-free labeling rule by 5 August 2014.

### CONFLICT OF INTEREST

Tricia Thompson is the owner/founder of Gluten Free Watchdog, LLC, Manchester, MA, USA. The other author declares no conflict of interest.

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### REFERENCES

- 1 U.S. Food and Drug Administration Federal Register. Final Rule; Document 78 FR 47154: Food Labeling; Gluten-Free Labeling of Foods. <https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>. Accessed 6 May 2014.
- 2 U.S. Food and Drug Administration Questions and Answers: Gluten-Free Food Labeling Final Rule. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm>. Accessed 6 May 2014.
- 3 Thompson T, Grace T. Gluten content of selected labeled gluten-free foods sold in the US. *Pract Gastroenterol* 2013; **37**: 10–16.
- 4 R-biopharm. Ridascreen Gliadin Available at <http://www.r-biopharm.com/products/food-feed-analysis/allergens/gliadin-gluten/item/ridascreen-gliadin>. Accessed 6 May 2014.
- 5 R-biopharm. Ridascreen Gliadin Competitive Available at <http://www.r-biopharm.com/products/food-feed-analysis/allergens/gliadin-gluten/item/ridascreen-gliadin-competitive>. Accessed 6 May 2014.
- 6 Thompson T, Mendez E. Commercial assays to assess gluten content of gluten-free foods: why they are not created equal. *J Am Diet Assoc* 2008; **108**, 1682–1687.
- 7 Thompson T, Lee AR, Grace T. Gluten contamination of grains, seeds, and flours in the United States: a pilot study. *J Am Diet Assoc* 2010; **110**, 937–940.
- 8 Packaged Facts. Gluten-Free Foods and Beverages in the US, 4th Edition, 2012. <http://www.packagedfacts.com/gluten-free-foods-7144767/>. Accessed 2 June 2014.
- 9 United States Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Regulatory Policy and Social Sciences, Economics Staff. Food Labeling; Gluten-Free Labeling of Foods, Docket No. FDA-2005-N-0404, Final Regulatory Impact Analysis, Regulatory Flexibility Analysis. <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM363530.pdf>. Accessed 29 May 2014.
- 10 Gluten-Free Certification Organization GFCO website [www.gfco.org](http://www.gfco.org). Accessed 6 May 2014.
- 11 Celiac Sprue Association CSA website [http://www.csaceliacs.info/csa\\_recognition\\_seal.jsp](http://www.csaceliacs.info/csa_recognition_seal.jsp). Accessed 6 May 2014.
- 12 Gluten Free Certification Program GFCP website <http://www.gf-cert.org/>. Accessed 6 May 2014.
- 13 US Food and Drug Administration Code of Federal Regulations. Malt. 21CFR184.1443a. Revised April 1, 2013. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=184.1443a&SearchTerm=malt>. Accessed 6 May 2014.
- 14 US Food and Drug Administration Code of Federal Regulations. Malt Syrup/Malt Extract. 21CFR184.1445. Revised April 1, 2013. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=184.1445&SearchTerm=malt>. Accessed 6 May 2014.
- 15 Gluten Free Watchdog Product alert: Greens Plus bar contains malt yet labeled gluten-free. <https://www.glutenfreewatchdog.org/blog/Product-alert-Greens-Plus-bar-contains-malt-yet-labeled-gluten-free/35>. Accessed 6 May 2014.
- 16 Gluten Free Watchdog Product alert: Boulder Canyon malt vinegar chips. <https://www.glutenfreewatchdog.org/blog/Gluten-Free-Watchdog-Product-Alert-Boulder-Canyon-Malt-Vinegar-Chips/32>. Accessed 6 May 2014.
- 17 Gluten Free Watchdog Product labeled gluten-free contains barley malt extract. <https://www.glutenfreewatchdog.org/blog/Product-Labeled-Gluten-Free-Contains-Barley-Malt-Extract-/11>. Accessed 6 May 2014.
- 18 Gluten-Free Dietitian Barley malt extract in Van's products. <http://www.glutenfreedietitian.com/newsletter/barley-malt-extract-and-vans-products/>. Accessed 6 May 2014.
- 19 Gluten Free Watchdog Boulder Canyon chips and FDA webinar statement on use of malt extract in gluten-free foods. <https://www.glutenfreewatchdog.org/blog/Boulder-Canyon-Chips--FDA-Webinar-Statement-on-Use-of-Malt-Extract-in-Gluten-Free-Foods/33>. Accessed 6 May 2014.
- 20 Medical Nutrition Practice Group Webinar: new rules for gluten-free labeling: get the facts from the experts. <http://www.mnpgdpg.org/node/270>. Accessed 12 March 2014.

- 21 US Food and Drug Administration Center for Food Safety and Applied Nutrition. Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282). August 2004. <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM179394.pdf>. Accessed 6 May 2014.
- 22 Gluten-Free Dietitian Can products containing wheat and barley grass be labeled gluten-free. <http://www.glutenfreedietitian.com/newsletter/2010/09/20/can-products-containing-wheat-and-barley-grass-be-labeled-gluten-free/>. Accessed 6 May 2014.

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