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Gluten Content of Selected Labeled Gluten-Free Foods Sold in the US

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The Food and Drug Administration (FDA) recently released the long awaited rule on the labeling of food as gluten-free. Labeled gluten-free food regulated by the FDA and sold in the United States must contain less than 20 parts per million (ppm) of gluten. The objective of this evaluation is to assess the actual gluten content of labeled gluten-free foods sold in the United States, as there is very little publicly available data.

INTRODUCTION

In 2004, under the Food Allergen Labeling and Consumer Protection Act (FALCPA),[1] the FDA was tasked with issuing a rule "to define, and permit the use of, the term 'gluten-free' on the labeling of foods." In 2007, the FDA published in the Federal Register a proposed rule to define gluten-free (GF) for voluntary use on food labels.[2] The long-awaited final rule for the *voluntary* labeling of food as GF was published on August 5, 2013.[3] The rule becomes effective on September 4, 2013 and food labels carrying a GF claim must be in compliance with the rule by August 5, 2014.

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Under this rule, food may be labeled GF if it is inherently GF (e.g., bottled water, raw carrots) or if it meets all of the following criteria:

1. does not contain an ingredient that is a gluten-containing grain (i.e., wheat, barley, rye, or crossbred hybrids of these grains such as triticale)
2. does not contain an ingredient derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour)
3. does not contain an ingredient derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch) if use of that ingredient causes the food to contain 20 ppm or more gluten.

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In addition, any unavoidable gluten in a food labeled gluten-free due to cross contact or migration of gluten from packaging materials must be < 20 ppm gluten. Of note, under the FDA rule, manufacturers are not required to test food carrying a GF claim for gluten.

There are a couple of additional criteria that also must be followed. The terms "no gluten," "free of gluten," and "without gluten" are considered synonymous with "gluten-free" when used on a food label. Products using these alternative terms must be in compliance with the gluten-free labeling rule. In addition, if a food is labeled gluten-free and also includes the word "wheat" in the ingredient list or "Contains" statement due to the use of ingredients such as wheat starch, the word "wheat" must be followed by an 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."

The GF labeling rule applies to foods and supplements as packaged and regulated by the FDA (including dietary supplements) that are intended for human use and sold in the United States (made domestically or imported). The rule does not apply to foods regulated by the United States Department of Agriculture, alcoholic beverages regulated by the Alcohol Tobacco Tax and Trade Bureau, cosmetics, prescription and non-prescription drugs, and pet food.

What is the Gluten Content of Labeled Gluten-Free Foods Sold in the US?

The FDA has stated that they adopted a < 20 ppm gluten threshold as one of the criteria for a food to be labeled GF "because the agency relies upon scientifically validated methods for enforcing its regulations. Analytical methods that are scientifically validated to reliably detect gluten at a level lower than 20 ppm are not currently available.[4]" They also state that "some celiac disease researchers and some epidemiological evidence suggest that most individuals with celiac disease can tolerate variable trace amounts and concentrations of gluten in foods (including levels that are < 20 ppm gluten) without causing adverse health effects.[4]" In addition, during the rule-making period, the FDA voiced concern that if the gluten threshold was set lower than 20 ppm gluten, it could adversely impact the ability of manufacturers to produce GF food.[5]

There is little publicly available published data on the gluten content of labeled GF foods sold in the United States. As a consequence, the amount of gluten in labeled GF foods is unknown. The purpose of this investigation was to assess the gluten content of labeled GF foods sold in the United States.

Description of Evaluation

Between April 2011 and May 2013 foods labeled GF were purchased from retail establishments in the US, including grocery stores and online merchants. The only requirement for purchase was that the product was labeled GF. 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, Massachusetts. Products tested included baking ingredients, beans, beverages, breads, cookies, entrees, flours, grains, gravy, hot cereals, baking mixes, nut products, pastas, ready-to-eat cereals, snack bars, crackers, tortilla chips, soups, and tortillas. Each product was purchased in triplicate (e.g., three boxes of cereal, three packages of noodles, etc). Different product lots were purchased whenever possible. Products were sent unopened to the food allergen testing facility Bia Diagnostics in Burlington, Vermont. Each product sample was tested in duplicate (two extractions) for a total of six extractions for each product. Testing in duplicate is done to guard against lab error and to ensure the sample being tested is homogenized (e.g., that any gluten contamination is evenly distributed in the sample). Samples were tested 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 kit manufacturer's directions (R-biopharm, Darmstadt, Germany).[6] The R5 ELISA was validated in a collaborative trial and uses the gliadin standard developed by the Prolamin Working Group.[7,8] The R5 ELISA has been endorsed by the Codex Committee on Methods of Analysis and Sampling as a type 1 method for determination of the gluten content in GF foods and is the method for determination of gluten in Codex Standard 118-1979 (Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten).[9,10]

Findings and Discussion

Three hundred and thirty-six packages of food

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Table 1. Gluten Content of Labeled Gluten-Free Foods Tested Between April 2011 through May 2013

Product (number of products)*	Extractions** < 5 ppm gluten	Extractions 5 to < 20 ppm gluten	Extractions ≥ 20 ppm
Baking (2)	12/12	0/12	0/12
Beans (1)	6/6	0/6	0/6
Beverages (1)	6/6	0/6	0/6
Breads (8)	42/48	4/48	2/48
Chili (1)	6/6	0/6	0/6
Cookies (12)	66/72	0/72	6/72
Entree (1)	6/6	0/6	0/6
Flours (9)	40/54	14/54	0/54
Grains (6)	36/36	0/36	0/36
Gravy (2)	12/12	0/12	0/12
Hot cereal (6)	27/36	4/36	5/36
Baking mix (11)	60/66	6/66	0/66
Nut products (1)	6/6	0/6	0/6
Pasta (8)	48/48	0/48	0/48
Ready-to-Eat Cereal (8)	48/48	0/48	0/48
Snack food (24)	134/144	10/144	0/144
Soup (5)	30/30	0/30	0/30
Tortillas (6)	24/36	8/36	4/36
Totals	**609/672**	**46/672**	**17/672**

* 112 separate products were tested in triplicate (336 total packages of food). Each sample was tested in duplicate (total of 672 extractions). For names of products tested see https://www.glutenfreewatchdog.org/browse.php

** X/Y where Y represents the total number of extractions (number of products x 6 extractions) and X represents the number of extractions falling within each category of test findings.

representing 112 different products were tested in duplicate for a total of 672 extractions (Table 1). Of the 672 extractions, 609 or 90.6% tested below the lower limit of quantification for the assay used (5 ppm gluten); 46 or 6.8% tested between 5 and < 20 ppm gluten (range 6 to 19); 17 or 2.5% tested ≥ 20 ppm gluten (range 26 to over 100). Of the 112 products tested, 36 (32%) were certified GF by either the Gluten Free Certification Organization (32 products) or the Celiac Sprue Association (4 products). Only four products (i.e., bread, hot cereal, tortilla, cookie) from three manufacturers tested at or above 20 ppm gluten. Three of these products were not certified GF; one product was certified GF.

While 9.4% of extractions contained quantifiable gluten, the vast majority of manufacturers are in compliance with the Food and Drug Administration's GF labeling rule. 97.5 percent of extractions tested below 20 ppm gluten. Of the extractions in compliance, 93% tested below 5 ppm gluten, which is the lower limit of quantification for the assay used.

To the best of the authors' knowledge, there are no published peer-review studies in the scientific literature on the gluten content of labeled GF foods sold in the US. A recent study assessed the gluten content of 205 labeled GF foods sold in the European countries of Italy, Spain, Germany, and Norway.[11] The study reported that 99.5% of samples tested below 20 ppm gluten and 94% of samples tested below 5 ppm. These findings are consistent with the findings reported in the present study.

Currently there are a few organizations certifying foods as GF in the United States, including the Gluten-Free Certification Organization (GFCO), the Celiac Sprue Association (CSA), and the Gluten-Free Certification Program (GFCP). One criterion for certification through GFCO is that foods contain less than 10 ppm gluten. According to the company website (www.gfco.org), GFCO certifies 13,000 products. One criterion for certification through CSA is that foods contain less than 5 ppm gluten. Based on information provided on their website (www.csaceliacs.org), over 100 manufacturers participate in CSA's certification program. The number of products this represents is not provided. One criterion for certification through GFCP (http://www.glutenfreecertification.ca/) is that foods contain less than 10 ppm gluten (this is a new program in the United States). The FDA has not objected to these certification programs or their individual requirements for certification.

The present evaluation does have limitations. Only a small fraction of available labeled GF foods were tested. As a result, the findings of this study may not be representative of the gluten content of labeled GF foods as a whole. Test results also provide a snapshot picture of the gluten content of each product at one point in time. There is no way to know without testing many more samples whether the gluten content of the three samples tested is truly representative of the gluten content of that product as a whole.

CONCLUSION

Based on the findings of this evaluation, manufacturers are not only capable of producing food with a lower threshold level of gluten than is currently allowed by the FDA, but are doing so already. GF consumers can take comfort in the knowledge that the vast majority of manufacturers who are designating food as GF are complying with the FDA's labeling rule.

If consumers have a concern about the gluten content of a GF product they can contact the manufacturer and ask about the steps taken to ensure foods contain < 20 ppm gluten. Even though testing is not required under the FDA's GF labeling rule, consumers can still inquire about a manufacturer's testing protocol, including the specific assay used and frequency of testing. ■

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Answers to this month's crossword puzzle:

1 P	E	2 R	C	3 U	T	4 A	5 N	6 E	O	7 U	S		8 G	9 O
E		E		P		10 N	O	N		N		11 P		S
12 R	E	L	A	P	S	E		D		13 C	R	E	A	M
I		Y		E		M		14 O	15 I	L		L		O
16 S	O		17 B	R	E	I		18 C	U	E		19 L	20 A	T
T		21 E				22 A	23 I	L		A		24 E	P	I
25 A	26 N	N	27 U	A	L		28 F	I	B	R	29 O	T	I	C
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40 S	I	R		41 C	A	N	N	U	L	A	T	I	O	N
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45 T	M	S		46 S	U	T	U	R	E	S		47 D	N	A

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