

PERSPECTIVE

Allergen advisory statements for wheat: do they help US consumers with celiac disease make safe food choices?

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In 2004, the Congress of the United States amended the Federal Food, Drug and Cosmetic Act to require foods under the labeling jurisdiction of the Food and Drug Administration (FDA) to state in plain English on the product label when an ingredient in a food is or contains any of eight major allergens.¹ Allergens that must be named are wheat, milk, eggs, soybeans, peanuts, tree nuts, Crustacean shellfish and fish. These allergens can be included in either the ingredients list (for example, glucose syrup from wheat) or a separate Contains statement (for example, Contains: wheat). All foods labeled on or after 1 January 2006 must be in compliance.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) applies to allergens in ingredients only. It does not apply to allergens that may be in a product unintentionally due to cross contact. Cross contact with allergens may occur anywhere along the food production line from the field where food is grown to the plant where food is processed.² Manufacturers sometimes use precautionary allergen advisory statements (for example, Made in a facility that also processes wheat) on product labels to alert consumers to food processing practices that may result in cross contact with allergens.²

Allergen advisory statements are not the same as FALCPA. In the US, allergen advisory statements are voluntary and are not currently defined by any federal regulation.² The FDA has stated that allergen advisory statements should not be used as a substitute for Current Good Manufacturing Practices (CGMP).² As part of the Food Safety Modernization Act (FSMA), 'FDA's longstanding position that CGMPs address allergen cross contact is now explicit in the regulatory text'.^{3,4} Covered establishments must have a food safety plan in place that includes preventive controls for allergens. With the exception of small businesses, most companies must be in compliance with FSMA by September 2016. FSMA does not appear to directly address allergen advisory statements and it is unclear at this time how (if at all) they will be impacted. The FDA continues to state in recently updated guidance that allergen advisory statements must be truthful and not misleading.²

There is very little published data on whether precautionary statements for wheat or gluten are helpful to consumers with celiac disease when deciding if a food is appropriate to eat. In a study on gluten contamination levels of 22 single-ingredient naturally gluten-free grains and flours not labeled gluten-free, 4 of the 7 products containing ≥ 20 parts per million (p.p.m.) gluten did not include an allergen advisory statement for wheat on product packaging.⁵ Three of the 13 products that contained less than the lower limit of quantification for gluten of 5 p.p.m., had an allergen advisory statement for wheat on the product label. The authors concluded that, 'The findings of this analysis suggest that

consumers cannot rely on voluntary advisory allergen labeling to make decisions on which inherently gluten-free grains, seeds and flours are free of gluten contamination.'

The purpose of the present study is to build upon this earlier research by reviewing the labeling claims and testing data of products not labeled gluten-free but appearing to be free of gluten-containing ingredients.

ALLERGEN ADVISORY STATEMENT LABEL REVIEW

Labeling information compiled for 101 products tested for gluten content was retrospectively reviewed for an allergen advisory statement for wheat, gluten or both. Products reviewed for this analysis were not labeled gluten-free but appeared to be free of gluten containing ingredients based on a review of the ingredients list (that is, no wheat, barley, rye, malt, brewers yeast). Products containing oats are generally advised against in the US unless labeled gluten-free.⁶ However, certain oat products and ingredients not labeled gluten-free were tested and included in this label review because they are either labeled/advertised as wheat-free, labeled no gluten ingredients used or are an ingredient sometimes used in gluten-free foods without regard to gluten-free status (that is, oat fiber). Precautionary labeling information was recorded after the product was purchased. Only precautionary labeling information included on product packaging was used. Allergen advisory statements from the manufacturer website were not included.

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 not labeled gluten-free or low gluten at the time of this analysis were included in this review. Products are 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 is received from a member of Gluten Free Watchdog. Product labels are not reviewed for an allergen advisory statement before purchase.

Testing for gluten was done through 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). If the food was suspected of containing gluten protein fragments owing to the use of certain fermented or hydrolyzed ingredients (that is, yeast extract), it also was tested using the competitive R5 ELISA (Ridascreen Gliadin R7021) and extracted with ethanol following

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the kit manufacturer's directions. Gluten protein fragments cannot be adequately detected using a sandwich ELISA, so a competitive ELISA must be used. The lower limit of quantification for the sandwich R5 ELISA is 5 p.p.m. of gluten. The lower limit of quantification for the competitive R5 ELISA is 10 p.p.m. of gluten.

FINDINGS AND LESSONS LEARNED

As can be seen in Table 1, 87/101 (86%) products tested for gluten did not include an allergen advisory statement for wheat or gluten on product packaging. Fourteen (14%) products tested for gluten did include an allergen advisory statement for wheat or gluten on product packaging. Of the 87 products that did not include an advisory statement, 13 (15%) contained quantifiable gluten at or above 5 p.p.m., including 4 (5%) products that tested at or above 20 p.p.m. of gluten. Of the 14 products that did include an advisory statement, only 1 (7%) contained quantifiable gluten at or above 5 p.p.m. (this product contained at or above 20 p.p.m. of gluten).

Products containing quantifiable gluten (range 5 p.p.m. gluten to >84 p.p.m.) included oats, spices, seasoning mixes, lentils, green tea leaves and a snack food (Table 2). Only the snack food included an allergen advisory statement for wheat. Allergen advisory statements for wheat or gluten included on product packaging included 8 precautionary statements for shared facilities and 5 precautionary statements for shared equipment (Table 3). One statement read, 'May contain traces of wheat.'

In this database review, precautionary labeling for wheat or gluten on products not labeled gluten-free but appearing to be free of gluten-containing ingredients was not a useful predictor of gluten content. In some cases, consumer reliance on precautionary statements for wheat or gluten could have resulted in choosing a product contaminated with gluten. A brand of oat fiber with precautionary labeling for wheat tested below 5 p.p.m. of gluten, whereas a brand of oat fiber without precautionary labeling tested above 84 p.p.m. of gluten (Tables 2 and 3).

LIMITATIONS

This assessment involved 101 foods. Findings are not necessarily representative. A much larger study is necessary to determine the usefulness of precautionary statements for wheat or gluten on packaged foods not labeled gluten-free but appearing to be free of gluten-containing ingredients.

It is not possible to determine from this study where in the food production line products became contaminated. Studies are necessary to determine the impact of tighter grain standards for allergens and robust allergen control programs on allergen cross contact.

It is important to note that the lack of an allergen advisory statement for wheat does not mean that a food is free of contamination from barley or rye. In the US, barley and rye do not fall under FALCPA and if an ingredient is made from one of these two grains, they do not need to be specifically named in the ingredients list. For example, malt is the common or usual name for barley malt but the word barley does not need to be included

on the label. As a result, manufacturers may not consider these grains as potential allergens or sources of gluten when deciding upon whether or what to include in a precautionary statement.

PRECAUTIONARY LABELING ON SINGLE INGREDIENT FOODS

Seven of the 14 foods with quantifiable gluten in this assessment are single-ingredient foods (that is, oat fiber, spices, green tea leaves). Many single-ingredient foods are considered by consumers to be naturally gluten-free. However, US grain standards allow certain percentages of foreign material (including grain) in grains, seeds and legumes.⁷ Foreign grain is not considered an ingredient and it is not included in the ingredients list. Gluten contamination of single ingredient foods may take place in the field, during harvest or during transport before a food arrives at the food processing plant.⁸ Precautionary labeling for wheat on packaged grains and legumes may or may not be included. It will be interesting to assess whether the FSMA leads to any changes in grain standards and how potentially contaminated grains are handled at the mill.

Many gluten-free consumers are aware of cross contact concerns with oat grain but fewer may be aware of contamination concerns with other grains and legumes. Because of the high risk of cross contact with wheat, barley or rye, the Academy of Nutrition and Dietetics (AND) recommends that only oats labeled gluten-free be eaten by individuals with celiac disease.⁶ It is also recommended by AND that whenever possible consumers should choose labeled gluten-free grain foods.⁶ There are no similar recommendations for legumes, spices and tea leaves.

PRECAUTIONARY LABELING ON FOODS LABELED GLUTEN-FREE

Allergen advisory statements for wheat are currently allowed on foods labeled gluten-free in the US.⁸ Foods with precautionary statements for wheat that are also labeled gluten-free must comply with the gluten-free labeling rule and contain < 20 p.p.m. of gluten. Unlike FALCPA, which applies to allergens in ingredients only, the gluten-free labeling rule applies to gluten that may be in a food due to ingredients and cross contact. Regardless, foods labeled gluten-free that also carry precautionary labeling may be particularly confusing to consumers with celiac disease. The FDA has stated that the Agency, '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.'⁸

There is very little data on the use of precautionary statements for wheat or gluten on labeled gluten-free foods and whether the use of such statements is associated with a higher level of gluten in food. Snack bars labeled gluten-free and tested for gluten through Gluten Free Watchdog were reviewed for allergen advisory statements for wheat or gluten. Twenty bars were tested and all bars had a gluten level below 20 p.p.m. of gluten.⁹ Five of the 20 bars contained an allergen advisory statement for wheat on product packaging. In this category of food an allergen advisory

Table 1. Summary findings of foods not labeled gluten-free but appearing to be free of gluten-containing ingredients (no wheat, barley or rye)

	< 5 p.p.m. of gluten	5 to < 20 p.p.m. of gluten	≥ 20 p.p.m. of gluten
Number of products (n = 101)	87	9	5
Allergen advisory statement for wheat/gluten (n = 14)	13	0	1
No allergen advisory statement for wheat/gluten (n = 87)	74	9	4

Abbreviation: p.p.m., parts per million.

Table 2. Products not labeled gluten-free but appearing to be free of gluten-containing ingredients that contained quantifiable gluten ($n = 14/101$)

Product name	Date of test	Assay used and extraction solution	Extraction 1 p.p.m.	Extraction 2 p.p.m.	Mean p.p.m.	FALCPA ^a food allergen labeling for wheat (i.e., Contains wheat)	Allergen advisory statement that includes wheat or gluten (i.e., may contain wheat)	Ingredients
Breakfast cereal	08/21/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	> 84	> 84	> 84	None	None	Organic oat bran, organic whole grain oat flour, organic fruit juice concentrate (organic pear or apple juice), organic whole grain oat flakes, sea salt, ascorbic acid (vitamin C) and natural vitamin E (to preserve freshness) Coriander seed
Spice	09/18/2013	Sandwich R5 ELISA (R7001) with cocktail extraction	10	7	8.5	None	None	Potato starch, dehydrated potato, high oleic expeller pressed sunflower oil or safflower oil, rice flour, salt, dehydrated garlic, dehydrated vegetables (tomato, green pepper, spinach, celery), dehydrated parsley, extractives of paprika and turmeric, vegetable extracts for coloring (radish, apple, black current), potassium chloride, sea salt
Savory snack food	02/12/2016	Sandwich R5 ELISA (R7001) with cocktail extraction	58	62	60	None	May contain traces of wheat	Sage Thyme
Spice	10/18/2013	Sandwich R5 ELISA (R7001) with cocktail extraction	8	7	7.5	None	None	Sugar, salt, brown sugar, spices, onion, garlic, maple syrup, red bell peppers, orange peel, paprika, safflower and sunflower oil, molasses, chili pepper, caramel color, natural smoke flavor and natural flavor
Spice	11/4/2013	Sandwich R5 ELISA (R7001) with cocktail extraction	5	14	9.5	None	None	Yellow corn meal, chili powder, maltodextrin, corn starch, cumin, dried onion, garlic powder, potassium chloride, yeast extract, onion powder, sugar, black pepper, citric acid, oregano, red pepper, celery seed
Seasoning mix	08/15/2013	Sandwich R5 ELISA (R7001) with cocktail extraction	8	< 5	—	None	None	There is no ingredients list on product packaging. The manufacturer website states, "... oat fiber is naturally produced from food-grade oat hulls through a proprietary process. This is a chemical-free process, turning organic hulls into various organic fibers."
Seasoning mix	07/24/2014	Sandwich R5 ELISA (R7001) with cocktail extraction and milk additive	84	> 84	—	None	None	Fenugreek Green tea
Oat fiber	07/24/2014	Competitive R5 ELISA (R7021) with ethanol and fish gelatin extraction mixture	> 270	> 270	> 270	None	None	Green tea
Oat fiber	01/14/2015	Sandwich R5 ELISA (R7001) with cocktail extraction	> 84	> 84	> 84	None	None	Green tea
Spice	11/9/2013	Sandwich R5 ELISA (R7001) with cocktail extraction	9	15	12	None	None	Green tea
Green tea leaves	07/16/2014	Sandwich R5 ELISA (R7001) with cocktail extraction and milk additive	> 84	> 84	> 84	None	None	Whole rolled oat groats, cane sugar, pecans, freeze-dried raspberries, freeze-dried strawberries, freeze-dried blackberries and sea salt
Green tea leaves	08/17/2015	Sandwich R5 ELISA (R7001) with cocktail extraction and milk additive	14	13	13.5	None	None	Whole rolled oat groats, cane sugar, dried sweetened cranberries (cranberries, sugar), sundried seedless raisins, brown flax seeds, sunflower seeds, almonds, walnuts, freeze-dried blueberries, cinnamon, sea salt
Oat cereal	01/01/2016	Sandwich R5 ELISA (R7001) with cocktail extraction	7	< 5	—	None	None	Water, organic lentils, sea salt
Oat cereal	02/04/2016	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	10	—	None	None	
Legume	04/13/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	9	7	8	None	None	

Abbreviation: p.p.m, parts per million. ^aFALCPA: Food Allergen Labeling and Consumer Protection Act.

Table 3. Products not labeled gluten-free but appearing to be free of gluten-containing ingredients that include an Allergen Advisory Statement for wheat or gluten ($n = 14/101$)

Product name	Date of test	Assay used and extraction solution	Extraction 1 p.p.m.	Extraction 2 p.p.m.	Mean p.p.m.	FALCPA ^a food allergen labeling for wheat (i.e., Contains: wheat)	Allergen advisory statement that includes wheat or gluten (i.e., may contain wheat)	Ingredients
Beverage mix	10/29/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	This product is manufactured in a facility that makes products containing milk, eggs, soy and wheat	Maltodextrin, malic acid, apple juice solids, caramel color, aspartame, sodium citrate (controls acidity), tricalcium phosphate (prevents caking), ascorbic acid, natural and artificial flavors, spice extractive
Candy	09/18/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	This product was manufactured in a facility where milk, eggs, tree nuts, peanuts, wheat and soy are used in the production of other products	Sugar, corn syrup, confectioner's glaze, salt, dextrose, gelatin, sesame oil, artificial flavor, honey, yellow 6, yellow 5, red 3
Nut	04/30/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	Manufactured on shared equipment, may contain other tree nuts, peanuts, wheat, soy, milk or sesame seeds	Walnuts, BHT (0.02%) added to preserve freshness
Savory snack	02/12/2016	Sandwich R5 ELISA (R7001) with cocktail extraction	58	62	60	None	May contain traces of wheat	Potato starch, dehydrated potato, high oleic expeller pressed sunflower oil or safflower oil, rice flour, salt, dehydrated garlic, dehydrated vegetables (tomato, green pepper, spinach, celery), dehydrated parsley, extractives of paprika and turmeric, vegetable extracts for coloring (radish, apple, black current), potassium chloride, sea salt 100% Oat fiber
Oat fiber	01/30/2015	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	Made in a plant that processes soy, wheat, eggs, milk	Sugar, cocoa processed with alkali, soy lecithin, carrageenan, salt, artificial flavors, spice, vitamins and minerals: calcium carbonate, ascorbic acid (vitamin C), zinc oxide, pyridoxine hydrochloride (vitamin B6), copper gluconate, manganese sulfate, biotin
Beverage mix	07/29/2014	Sandwich R5 ELISA (R7001) with cocktail extraction and milk additive	< 5	< 5	< 5	None	Made on equipment that also processes milk, wheat and soy	Gluten-free oats, sorghum flour, white rice flour, potato starch, arrowroot, soy free Earth Balance (natural oil blend (palm fruit, canola and olive oils), filtered water, pure salt, contains < 2% of natural flavor (no MSG, no alcohol, no gluten), sunflower lecithin, lactic acid (non dairy derived from sugar beets) and colored with annatto extract), organic shortening (organic palm oil), organic cane sugar, organic molasses, organic brown sugar, organic flax seeds, ricemellow cream (brown rice syrup, soy protein, natural flavors, natural gum), organic vanilla, organic cinnamon, baking soda, sea salt, xanthan gum.
Bakery product	09/25/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	Made in a facility that processes gluten	Soy free Earth Balance (natural oil blend (palm fruit, canola and olive), filtered water, salt, contains < 2% of natural flavor (no MSG, no alcohol, no gluten), sunflower lecithin, lactic acid (non dairy derived from sugar beets) and colored with annatto extract), organic cane sugar, organic safflower oil, organic shortening (organic palm oil), organic peanut butter, organic cocoa powder, organic coconut flour, white rice flour, tapioca starch, organic corn starch, Enjoy Life chocolate (sugar, chocolate liquor, cocoa butter), non-gmo rice milk (water, brown rice, expeller pressed high oleic safflower oil, tricalcium phosphate, natural vanilla flavor, sea salt, vitamin A palmitate, vitamin D2, vitamin B12), organic vanilla, organic lemon juice, baking soda, baking powder, sea salt, xanthan gum
Bakery product	09/25/2014	Sandwich R5 ELISA (R7001) with cocktail extraction and milk additive	< 5	< 5	< 5	None	Made in a facility that processes gluten	

Table 3. (Continued)

Product name	Date of test	Assay used and extraction solution	Extraction 1 p.p.m.	Extraction 2 p.p.m.	Mean p.p.m.	FALCPA ^a food allergen labeling for wheat (i.e., Contains: wheat)	Allergen advisory statement that includes wheat or gluten (i.e., may contain wheat)	Ingredients
Bakery product	09/25/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	Made in a facility that processes gluten	Soy free Earth Balance Inatural oil blend (palm fruit, canola and olive), filtered water, salt, contains less than 2% of natural flavor (no MSG, no alcohol, no gluten), sunflower lecithin, lactic acid (non dairy derived from sugar beets) and colored with annatto extract), organic cane sugar, sorghum flour, brown rice flour, white rice flour, potato starch, assorted flavors jam (organic raspberries, organic apricot, organic strawberries, organic blueberries, cherries, organic cane sugar, natural fruit pectin, ascorbic acid, citric acid), organic vanilla, organic flax, baking powder, sea salt, xanthan gum.
Savory snack	08/28/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	Manufactured in a facility that also processes wheat, soy and milk	Veggie straws (potato flour, potato starch, corn starch, tomato paste, spinach powder, salt, sugar, beetroot powder (color), turmeric), canola oil and/or safflower oil and/or sunflower oil, sea salt Husk of psyllium seeds
Psyllium husk	11/19/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	This product was packaged using equipment that also handles wheat, soy, peanuts and tree nuts	Split matpe (no skin)
Bean	08/05/2014	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	This product was processed on machinery that also processes wheat, peanuts and tree nuts	Cashews
Nut	05/31/2013	Sandwich R5 ELISA (R7001) with cocktail extraction	< 5	< 5	< 5	None	Processed in a facility that processes wheat, eggs and peanuts	Chocolate (cocoa beans, sugar, cocoa butter, emulsifier (soya lecithin), natural vanilla extract), eggs, sugar, butter (pasteurized cream, natural flavorings (lactic acid, starter distillate, culturama), chocolate (sugar, unsweetened) chocolate, cocoa butter, soy lecithin, natural vanilla extract, salt), quinoa flour, amaranth flour, salt (magnesium carbonate), vanilla extract (water, alcohol, sugar, vanilla bean extractives)
Bakery product	02/13/2015	Sandwich R5 ELISA (R7001) with cocktail extraction and milk additive	< 5	< 5	< 5	None	All products are manufactured on shared equipment. May contain peanuts, tree nuts, wheat	

Abbreviation: p.p.m., parts per million. ^aFALCPA: Food Allergen Labeling and Consumer Protection Act.

statement for wheat was not an accurate predictor that a food would test at or above 20 p.p.m. of gluten.

In a study published in this Journal,¹⁰ 8 of 158 (5%) labeled gluten-free products contained gluten at or above 20 p.p.m. (that is, beverage, bread, bread coating mixture, crispbread, biscotti, hot cereal, spice and tortilla). None of these 8 foods contained an allergen advisory statement for wheat.¹¹ Allergen advisory statements for wheat or gluten were not useful predictors of whether a labeled gluten-free food was truly gluten-free in the referenced analysis.

CURRENT RECOMMENDATIONS REGARDING PRECAUTIONARY LABELING

The National Institute of Allergy and Infectious Disease recommends in the *Guidelines for the Diagnosis and Management of Food Allergy in the United States* that individuals should avoid foods with 'precautionary' labeling for allergens if they have an allergy to the named allergen.¹² Part of the rationale for this statement is that, 'FALCPA does not currently regulate voluntary disclaimers such as 'this product does not contain peanuts, but was prepared in a facility that makes products containing peanuts' or 'this product may contain trace amounts of peanut.' Such disclaimers can leave consumers without adequate knowledge to make objective decisions.' This recommendation is based on expert opinion only.

In terms of foods labeled gluten-free, consumers are advised to trust the label regardless of allergen advisory statements for wheat or gluten.¹³ This is due to the gluten-free labeling rule applying to both gluten in ingredients and gluten that may be found in a product due to cross contact. However, when it comes to foods not labeled gluten-free but appearing to be 'gluten-free' based on ingredients, there are no established guidelines for individuals with celiac disease on whether they should avoid products with allergen advisory statements for wheat or gluten.

FUTURE NEEDS

Ideally, allergen advisory statements should be used by manufacturers to help consumers make choices about which foods they can eat given their particular health constraints. The FDA should strongly consider regulating allergen advisory statements, especially in light of the FSMA. The language used by manufacturers in these statements should be standardized and have specific codified meaning.

The FDA should consider requiring precautionary statements under certain circumstances. This might include precautionary statements on single ingredient agricultural products that are more likely to be contaminated with any of the top 8 allergens or a gluten-containing grain. This also might include foods produced on the same production lines or using the same equipment as any of the top 8 allergens or gluten. FDA may want to require different language depending upon whether potential contamination is likely to have occurred in the field before arriving at the processing plant (as may be the case with grains) or at the processing plant (which may occur in shared facilities with allergens).

This distinction may be important to help determine whether Grain Inspection, Packers and Stockyards Administration (GIPSA) standards for allergenic grains and seeds need to be strengthened. There have been advances with mechanical and optical sorters that may allow more foreign material to be removed from grains, seeds and legumes. If raw ingredients arriving at a processing plant are free of allergens then there is a greater likelihood a processed food containing these raw ingredients will be free of allergens. This will be especially true now that the Food

Safety and Modernization Act is in effect. Manufacturers must now have a food safety plan in place that includes preventive controls for allergens.

Consumers with celiac disease must be educated regarding the risk associated with choosing a grain, seed and legume with a gluten-free label versus one without a gluten-free label. Presumably a manufacturer takes extra steps to ensure the gluten-free status of labeled gluten-free foods even when the food contains a precautionary statement for wheat. Consumers also must be educated regarding the standards of CGMP designed to reduce risk of cross contact even when precautionary statements for wheat are included on labels due to shared facilities, equipment or production lines.

Increased education is also required to let consumers know that FALCPA includes ingredients only and does not include allergens that may be in a product unintentionally due to cross contact. Increased education is also needed to let consumers know that a gluten-free label applies to gluten that may be in a product due to ingredients and cross contact and that regardless of the source of gluten the product must contain less than 20 p.p.m. gluten.

SUMMARY

On the basis of this analysis, the current use of allergen advisory statements for wheat or gluten are not useful predictors of whether or not a single or multi-ingredient food product contains 20 or more p.p.m. of gluten. Precautionary statements should be regulated and standardized so that they are helpful to the consumer.

CONFLICT OF INTEREST

Tricia Thompson is the owner/founder of Gluten Free Watchdog, LLC.

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