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Abstract

Gluten is a common protein found in wheat, rye, and barely. It can some-times be found in products that do not contain these grains. Gluten contamination in naturally gluten-free foods, products processed to remove gluten, and foods made with non-gluten derivatives is of concern for those suffering from an intolerance to gluten, such as Celiac disease. For these individuals, knowing whether or not food products advertised as "gluten-free" are truly so is necessary for their health and safety. The current study was designed to determine the reliability of "gluten-free" food labels in the consumer market-place. Samples of "gluten-free" foods were collected from a variety of locations in central Ohio, including grocery stores, health-food stores, and restaurants. A total of 168 samples were analyzed using a Nima Gluten Sensor (antibody-based colorimetric assay) to determine if gluten content was <20 ppm, the maximum allowed by US law for a product labeled "gluten-free". Of the samples tested, 98 were certified as "gluten-free" (<10 ppm) by the Gluten-Free Certification Organization (GFCO); only 13 of these (13.3% of samples) were found to exceed 20 ppm of gluten. By comparison, 115 samples were labeled "gluten-free" on the packaging but did not contain certification; of these, 33 (28.7%) were found to actually contain more gluten than allowed by law. Samples obtained from grocery stores (n=146) and health-food stores (n = 19) had relatively few positive results (14.4% and 15.8% respectively), whereas samples obtained from stores whose primary function is not to sell food (n = 41) were much more likely to exceed the federal limit on gluten (41.5% of samples). While results reveal that "certified gluten-free" products may be more trusted in their claim of being "gluten-free". contamination still poses some risk to those who are intolerant of gluten.

Introduction

Celiac disease is a genetically predisposed condition defined as a permanent intolerance to gluten; it affects 1% of the population in western countries (1-3) and can manifest as subtle or extreme. Celiac disease is characterized by the occurrence of gastrointestinal symptoms, including weight loss and chronic diarrhea (4), and limiting or avoiding gluten completely may reduce the risk for long term complications (5). Gluten is made up of proteins found in wheat, barley, rye, and triticale (6). On a biochemical level gluten is a mix of several protein components including gliadins, globulins, albumins, and glutenins (7). In food production it is used widely in baking as well as for modification of texture and form, as a substitute for animal protein in meat products, and as a filler in some drugs (8,9). Refraining from gluten ingestion is an important step for patients intolerant to gluten to prevent symptoms. There are several laws that have been put into place that assist consumers by regulating gluten-free foods. The FDA allows foods to be labeled "gluten-free", indicating that the food product must either be naturally gluten free or must comply with several rules. The gluten-free product must have no gluten-containing grains, no foods derived from glutencontaining grains that are processed to remove gluten, and must contain less than 20 ppm of gluten (10). Although gluten-free products are regulated in most countries, a few studies have demonstrated concerning levels of contamination in labelled "gluten-free" products. Due to the scarcity of data concerning gluten determination of labeled "gluten-free" foods and the high rate of contamination in previous studies, testing the reliability of products claiming to be gluten-free is imperative to ensure the safety of those intolerant to gluten. This study aims to shed light onto the mislabeling of several foods that are advertised as gluten-free as well as bring awareness to putting proper rules in place to alleviate this mistake

Gluten contamination: prevalence and risks associated with foods labeled "gluten-free"

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Materials & Methods

Our sample consisted of 222 food samples labeled "gluten-free" as well as one known gluten-containing sample (positive control). These samples were obtained from various retail establishments in 2019-2020 across the United States, including grocery stores, specialty/health-food stores, and stores whose primary sales are not food (such as dollar stores and home improvement stores). A few samples were also obtained from restaurants and bakeries. A NIMA brain gluten sensor was used to determine the presence or absence of gluten in each sample. Each test gives a gluten-positive or gluten-negative result. Sample capsules inserted into the NIMA device contain antibodies, a liquid extraction formula, and a test strip that develops and sends a visible result to the NIMA device (11). Samples for testing are approximately the size of a pea. Samples that are thick or dense require diluting by soaking in 100 mL of distilled water for about 1-2 minutes. Following sample application, the test sample is inserted into the NIMA sensor and twisted until the capsule produces an audible click, indicating that it has locked into place. Each sample is tested one time, and positive results yield a plant icon and the words "gluten found"; a negative sample vields a smile icon. The third option from the sensor is "No Test Result." indicating that the test is inconclusive. These samples were tested again, and if the sample yielded another "no result," then the testing proceeded.



Discussion

Samples that contained gluten contamination (positive results) were found in both certified and non-certified labelled "gluten-free" products. Specifically, contamination was present in 13.2% of certified samples and in 28.7% of noncertified samples (Table 1). These results were not unexpected; a study performed in Brazil that tested labelled "gluten-free" non-certified food products found that 11% of the samples contained gluten contamination, despite having a label (12). The results of the study aligns with the results of the current study: the most contaminated food groups were flours and starches, as well as cookies and muffins (Figure 1). From Table 2, the store types with the highest rate of positive samples per store were those where food was not their primary product (nonspecific) and restaurants, respectively (41.5%, 31.3%). In this study, a smaller percentage of certified products were contaminated with gluten, supporting the idea that certified products, which are assayed, are assumed to have a greater likelihood of meeting the standards set for gluten content (13). Due to the high level of foods found to contain gluten (1 in 5 samples), it is not uncommon for an individual practicing a gluten-free diet to experience a certain level of crosscontamination. There are several conditions that may produce a higher risk for contamination: "comingling" of grains in fields from crop rotation, sharing storage facilities, or using the same vehicles, equipment, and production facilities to transport and produce the gluten-free products (14). In order to abide by the 20 ppm gluten content limit proposed by the FDA, companies producing labelled "gluten-free" products must consider a certification process that includes testing samples for gluten content before and after production, as well as adopting proper manufacturing practices (15).

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