

PRINCIPLES OF GLUTEN-FREE PRODUCT CLAIMS/CERTIFICATION



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INTRODUCTION

Gluten, a mixture of proteins naturally occurring in wheat, rye, barley, and crossbreeds of these grains [1], has become a focal point of dietary discussions and health research in recent years. While it has been a staple in human diets for millennia, the modern era has seen a significant rise in awareness and diagnosis of gluten-related disorders. These include celiac disease, an autoimmune condition resulting in damage to the small intestine lining [2] affecting an estimated 1 in 133 Americans, or about 1% of the population [3], and non-celiac gluten sensitivity, which impacts a broader segment of individuals (estimates range from 1/2 - 6% of the population [4]) who experience adverse symptoms upon gluten consumption but don't have the same antibodies and intestinal damage seen in celiac disease. [5]

The increasing prevalence of both clinically diagnosed celiac disease and documented gluten sensitivity is due to expanded awareness of the symptoms and improved diagnostic techniques in the medical profession. [6] This has prompted extensive research into their causes, mechanisms, and impacts on health. Perceived benefits of a gluten-free diet include improved health, weight loss, and increased energy, but more research is needed to verify these benefits. [7] To make such a claim, it is important to consider both the consumer implications and the burden of proof a business bears.

CONSUMER IMPLICATIONS

Historically, gluten-free claims have been associated with gut health, weight loss, and as a panacea for various other health conditions. A gluten-free claim would then seem to be a positive statement that a brand can place on its packaging to drive sales. However, gluten-free products have typically not delivered exceptional consumer experiences (whether in taste, texture, aroma, or nutritional profile). As such, this product quality stigma MAY limit potential market appeal as “gluten-agnostic” consumers look to conventional products to ensure a positive product experience. In other words, thoughtfully consider the value of a “gluten-free” claim to your target consumer/market.

IMPLEMENTATION OF A GLUTEN-FREE CLAIM ON A PACK

Making a gluten-free claim on a food product is more complex than simply having all gluten-free ingredients. A brand must consider if any of your ingredients could have been made in a facility that also processes wheat or gluten-containing ingredients – if so, there may be cross-contamination, and your ingredient could, in fact, contain some amount of gluten. In addition, if you are producing your product in a shared space with other makers that may have a wheat or gluten-containing product, it is likely there is cross-contamination that must be disclosed to the consumer.

To make a gluten-free claim, you must confirm that none of your ingredients have gluten and that your product is not/cannot be cross-contaminated with gluten or other gluten-containing grains or flours. The brand is responsible for ensuring that the product contains less than 20 parts per million (ppm) gluten as defined by the Food & Drug Administration (FDA). [1] Typically, this is done by:

- Implementing an allergen management program to ensure that the finished product is free from the allergen of concern (in this case, gluten-containing ingredients), including segregation of allergenic materials and processing equipment, cleaning procedures, cleaning procedures validation and verification, employee training, and monitoring/documentation of the allergen management program. [8]
- Conducting ongoing finished product testing to ensure the product stays below the 20 parts per million (ppm) threshold. Several test methods exist for this purpose including methods such as Enzyme-Linked Immunosorbent Assay (ELISA) or lateral flow devices (LFD); DNA-based methods such as Polymerase Chain Reaction (PCR); Mass spectrometry (MS), and other non-specific methods such as protein tests. The choice of test method depends on the type of product, cost, and desired turnaround time. [9]

The allergen cleaning program and testing may not be necessary if the brand can verify in writing that its ingredients do not contain gluten (verification is typically available from ingredient suppliers) AND there is no possibility of cross-contamination in the production space. Despite these precautions, the brand would still be liable for damages or fines should the FDA conduct a marketplace audit and detect the presence of gluten above the 20 ppm threshold in the finished product carrying a gluten-free claim.

If interested, the Gluten-Free Certification Organization (GFCO) offers a third-party certification service [10], though the process is long, complex, and expensive.

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