

Voluntary Allergen Advisory Statements

Key Points

- Allergen advisory statements or “may contain” statements are sometimes printed on product labels. Examples you might see on a product include:
 - “Processed in a facility that also processes wheat”
 - “May contain wheat”
 - “Processed on shared equipment with wheat”
- Allergen advisory statements are different than regulated allergy statements such as “Contains Wheat.” See FALCPA question below.
- While allergen advisory statements might be concerning, it’s important to know that these statements are VOLUNTARY on the part of the manufacturer
- Manufacturers may choose not to include these voluntary allergen advisory statements on food labels even if their products are processed using shared equipment or facilities.
- Products with allergen advisory statements are not necessarily contaminated and products without them are not necessarily free of contamination.
- All food is required to be processed using current Good Manufacturing Processes (GMP), a regulation set by the FDA, to prevent unintentional ingredients, such as allergens, from ending up in a product.

How can a food be labeled gluten-free AND have an allergen advisory statement?

- When a product IS labeled gluten-free, under the FDA gluten-free labeling rule, the food must contain less than 20ppm. This rule applies even when an allergen advisory statement for wheat is also printed on the label. The FDA rule applies to gluten that is in a product intentionally (an ingredient) and unintentionally (through cross-contact).^{1, 2}
- Regardless of the label, it is always a good idea to ask the manufacturer about steps taken by the manufacturing company to avoid cross-contact.

How are allergen advisory statements for wheat different than the Food Allergen Labeling and Consumer Protection Act (FALCPA)?

- FALCPA is not voluntary for FDA-regulated foods. Under FALCPA,² if an ingredient in an FDA-

regulated packaged food product contains PROTEIN from wheat, the word “wheat” MUST be included on the food label either in the ingredients list or “Contains” statement.

- Please note that FALCPA applies to ingredients only. FALCPA does not apply to allergens (such as wheat) that may be in a food product unintentionally due to cross-contact.

I have a food allergy to wheat. How worried should I be about allergen advisory statements on foods?

- In 2010, The National Institutes of Health (NIH) released, Guidelines for the Diagnosis and Management of Food Allergy in the United States.³
- These guidelines recommend that products with allergen advisory statements be avoided by individuals with allergies to the allergens named in the allergen advisory statement. • For example, if there is an allergen advisory statement for wheat, the expert panel suggests that individuals allergic to wheat should avoid that product.
- These guidelines do not address allergen advisory statements for wheat for individuals with celiac disease. Dietary fiber is found in foods that come from **plants** such as fruits, vegetables, beans and legumes, nuts and seeds, and gluten-free whole grains.

I heard that some gluten-free grains might be contaminated with gluten. Wouldn't an allergen advisory statement help me figure that out?

- Not necessarily. In the study, “Gluten contamination of grains, seeds, and flours in the United States: A pilot study,” 22 naturally gluten-free grain products were tested for gluten.⁴
- Four of seven products containing >20 ppm of gluten did not contain an allergen advisory statement.
- Three of the 13 products that contained <5ppm of gluten had an advisory statement for wheat on the product label.
- In short, based on this study (and others like it), allergen advisory statements do not appear to be reliable for determining whether a food NOT labeled gluten-free is contaminated with gluten.^{1,4,5}
- Another study resulted in similar conclusions for foods labeled gluten-free with allergen advisory statements.⁷ The allergen advisory statements were not reliable for determining which products were contaminated with gluten.

Take Home Messages

- Allergen advisory statements are voluntary and unregulated.
- These statements are related to manufacturing practices.¹
- Allergen advisory statements do not appear reliable for determining whether foods labeled gluten-free or not labeled gluten-free are contaminated with gluten.^{1,4-6}
- Under the FDA’s labeling rule, food labeled gluten-free must contain < 20 ppm of gluten from ingredients and cross-contact regardless of whether the label includes an allergen advisory statement for wheat.

References

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6. Thompson T., Keller A., Lyons T. When foods contain both a gluten-free claim and an allergen advisory statement for wheat: should consumers be concerned? *Eur J Clin Nutr.* 2018;72(7):931-935.
