

Frequently Asked Questions about 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 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.

Q: 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.

Q: 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,³ 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.

Q: 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*.⁴

- 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.**

Q: 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.⁵

- 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.^{1,5, 6}
- Another recent 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.^{1,5, 6, 7}
- 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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