



FOOD CONSULTING... STRATEGICALLY
ALLERGEN PAL • FITNESS FOR PURPOSE IN TESTING



One test does not fit every allergen, or every food

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For quality managers and regulatory affairs staff at food manufacturers

The rules are being rewritten, right now

The science of how much of each allergen is safe, and the labels that warn about cross-contact, are converging. A parallel EU process is further behind.

THE SCIENCE · 2020-2025

1

FAO/WHO set the scientific basis

Reference doses for the priority allergens, including wheat, were set in 2022. **A separate 4 mg gluten dose for gluten-containing cereals followed in November 2025.**

THE GLOBAL STANDARD · THIS MONTH

2

Codex reaches final adoption

CCFL finalised the new guidelines. Codex adopted them at Step 8, CAC49 (Geneva, July 2026), as an annex to CXS 1-1985.

THE EU · BEHIND CODEX

3

A parallel process, at an earlier stage

The EU is developing similar rules, at an earlier stage. Adoption is expected in Q4 2027.

Every priority allergen now has a reference dose

The reference dose is the small amount of allergen protein below which most affected people are not expected to react. It sets the action level that decides whether a 'may contain' label is needed. Coeliac disease has its own panel.



IgE-mediated food allergy

mg total protein from the allergenic food

1.0	Almond, Brazil nut, Cashew, Pistachio, Macadamia, Pine nut, Walnut, Pecan, Celery, Mustard
2.0	Peanut, Egg, Milk, Sesame
3.0	Hazelnut
5.0	Wheat, Fish
10.0	Buckwheat, Lupin, Soy
200.0	Crustaceans



Gluten-containing Cereals

mg total gluten, all sources

4.0 mg

All relevant gluten sources:

wheat and other Triticum species; rye and other Secale species; barley and other Hordeum species, and their derived products.

Separate from wheat's IgE dose, which still applies.

Oats have no gluten reference dose of their own: coeliac reactions are attributed to cross-contact with wheat, barley or rye.

A number on a table needs a test behind it

Each reference dose only protects people if the allergen can be measured reliably in the product. Codex method experts confirmed at CCMAS45 that suitable methods exist, with one important caveat.

1 Reference dose

The safe amount of allergen protein, set by FAO/WHO.

2 Action level

Calculated from how much of the food is eaten in one sitting.

3 Your analytical result

Must reliably measure the allergen in your real product.



The caveat that matters to you

No single analytical method performs optimally across all food matrices and processing conditions. A method that is accurate for one allergen in one food can under-report or over-report it in another. Gluten, the subject of our published review, is the clearest worked example, but the same principle applies to every allergen in the tables.

Why one method cannot cover every food

With gluten as the worked example: the food itself, and how it was made, change which test is reliable. The same failure modes recur across other allergens.

1

Heating and processing

Baking or extrusion alters the allergen protein, so some tests no longer detect it. A different extraction or a different method is needed.

2

Fermentation and hydrolysis

The protein is broken into fragments and standard sandwich methods do not detect it. A different assay format is required.

3

Interfering ingredients

Polyphenols, tannins, fats, salt and acidity distort readings, over-estimating or under-estimating the true allergen content.

The bottom line: there is no universally valid method for all food matrices. The choice of method must follow the product.

Validation is not the finish line

A method can be fully validated in the laboratory and still be the wrong choice for your product. The real question is whether it is fit for purpose for your specific allergen, matrix and process.



Method validation alone

- Shows the method works under set conditions
- Often tested on a limited range of foods
- Says nothing about your specific matrix
- Can give false confidence in a result



Fitness for purpose

- Matches the method to the allergen
- Accounts for your food's actual matrix
- Accounts for how it was processed
- Verified for the product in front of you



This is the central message of our published review of gluten analysis.

Popping, Bartsch, Besler-Scharf, Diaz-Amigo, Hochegger, Meikle & Sykes (2026). Comprehensive Reviews in Food Science and Food Safety 25(4). doi.org/10.1111/1541-4337.70516



What this means for your site

BRCGS already asks for the right thing: the Global Standard Gluten-Free requires demonstrated fitness for purpose rather than mandating a single method. Your task is to apply this to every allergen you test.



The key question for your laboratory: do you use one method for all matrices and processing conditions, or is the method chosen and validated for each product? If it is the same method for everything, the results may not be reliable on your harder matrices.

1

Question your laboratory

Ask which method and extraction they use per allergen, validated for your matrix.

2

Scrutinise supplier claims

Treat 'may contain' as risk to verify.
Ask how, and against which dose, they assessed it.

3

Keep the audit trail

Document why each method was chosen for each product and allergen. You must be able to evidence that decision.



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