PRIMORIS
YOUR RELIABILITY IN FOOD ANALYSIS

Allergen analysis: why one size does not fit all

January 2026

Introduction

Food allergies are a growing public health concern worldwide. For affected consumers, even trace amounts of an allergen can lead to serious reactions, making accurate allergen management a critical element of food safety. As a result, quality assurance (QA) teams face increasing pressure to ensure correct labelling, prevent unintended cross-contamination and substantiate decisions with reliable analytical data.

Against this background, allergen analysis is often perceived as straightforward. Laboratories regularly receive requests such as: ***"Can you analyse the 14 allergens for me?"*** While understandable, this question also illustrates a widespread misconception. Allergen analysis is fundamentally different from the analysis of pesticides or contaminants, where clear legal limits and well-defined target molecules exist.

In reality, allergen analysis is a complex field where biology, food processing, analytical methodology and regulatory interpretation intersect. Understanding this complexity is essential to ensure that analytical results are not only technically correct, but also meaningful and fit for their intended purpose.

1. Allergen regulation: clear obligations, complex decisions

European Regulation (EU) No 1169/2011 defines 14 allergens that must be declared on food labels when deliberately used as ingredients. The objective is clear: to protect consumers by providing transparent and reliable information. Unlike with pesticide or contaminant legislation, concentration limits are not defined for most allergens.

This absence of thresholds has important consequences. While it is clear which allergens must be labelled when intentionally added, the regulation offers limited guidance on how to deal with unintended presence due to cross-contact or shared production environments. As a result, food business operators must assess risks themselves and decide how to translate analytical results into labelling decisions.

Adding to this complexity, allergen legislation and priorities differ between regions. While the European Union focuses on 14 allergens, other markets, such as the United States, apply different lists and requirements. This means that allergen relevance is not universal but depends on where products are marketed and consumed.

2. Allergen analysis is not one-size-fits-all

One of the main reasons allergen analysis is often misunderstood, lies in the nature of allergens themselves. Allergens are proteins, which are inherently sensitive to processing. Heat treatment, fermentation, changes in pH or mechanical processing can alter protein structures, affecting how easily they can be detected.

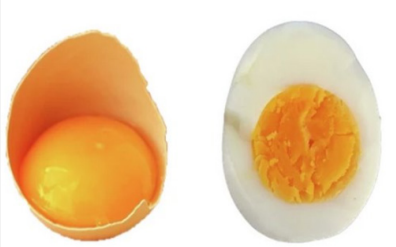

Figure. A simple analogy illustrates this well: just as an egg coagulates when exposed to high temperatures, allergenic proteins can also change structure when subjected to harsh processing conditions. These structural changes directly impact the suitability and performance of analytical methods.

This means that the same allergenic ingredient may behave very differently depending on how it is processed and incorporated into a food matrix. From an analytical perspective, this raises a key question:

What are we actually trying to measure?

The answer depends strongly on the purpose of the analysis. Allergen testing can be used for various objectives, such as verifying cleaning efficiency, investigating potential cross-contamination, supporting labelling decision or identifying hidden ingredients.

Each of these objectives requires different information and may call for different analytical approaches. Copying an analysis strategy from another company or product without considering these factors can easily result in misleading conclusions.

3. Understanding results starts with understanding methods

Several analytical techniques are commonly used in allergen analysis, each with its own strengths and limitations. Interpreting results correctly requires insight into what each method actually measures.

ELISA – the workhorse of routine allergen testing

Enzyme-Linked Immunosorbent Assay (ELISA) is the most widely used method for allergen analysis. It targets allergenic proteins using antibodies and provides quantitative results with high sensitivity. Its practicality and relatively fast turnaround time make it the preferred method for routine testing.

However, ELISA also comes with important challenges. The antibodies used in ELISA kits target specific parts of allergenic proteins, known as *epitopes*. The interaction between an antibody and an epitope is often described using a *lock-and-key principle*, where the antibody recognises a specific structural feature of the protein.

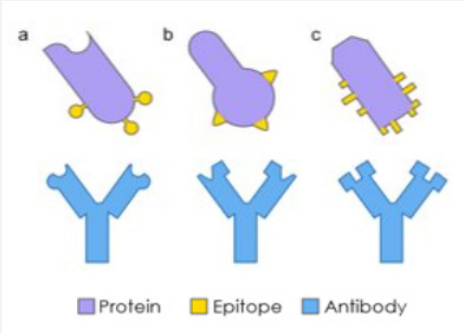

Figure. Antibody–epitope interaction often follows a lock-and-key principle.

The choice of antibody is made by the kit manufacturer and is often part of their intellectual property. As a result, not all ELISA kits use the same *lock,* even when analysing the same allergen. In addition, most allergens consist of multiple proteins, each containing several epitopes. Manufacturers must therefore make strategic choices about which targets to include.

Some ELISA kits use broader antibodies that recognise multiple related proteins, reducing the risk of missing an allergen but increasing the likelihood of cross-reactivity. Other kits use highly specific antibodies, which minimise false positives but may be more sensitive to processing effects, potentially leading to underestimation.

Figure. ELISA kit using broader antibodies (left) and kit using highly specific antibodies (right).

In addition, ELISA quantification depends on the reference material used for calibration. Highly purified proteins behave differently from protein extracts derived from real food matrices. As a result, different ELISA kits may produce different numerical results for the same sample, even though each result may be technically correct within its own context.

PCR – detecting what proteins may no longer reveal

Polymerase Chain Reaction (PCR) is fundamentally different from ELISA in that it targets DNA rather than proteins. Because DNA is generally more resistant to processing, PCR can be particularly useful for highly processed foods, detecting hidden or unexpected ingredients, or for identifying the species origin of an allergen. Moreover, PCR is often preferred when ELISA carries a high risk of cross-reactivity.

During the PCR process, short synthetic DNA primers selectively bind to allergen-specific DNA sequences and amplify them exponentially. Once sufficient genetic material is generated, the presence of the allergen source can be detected and interpreted.

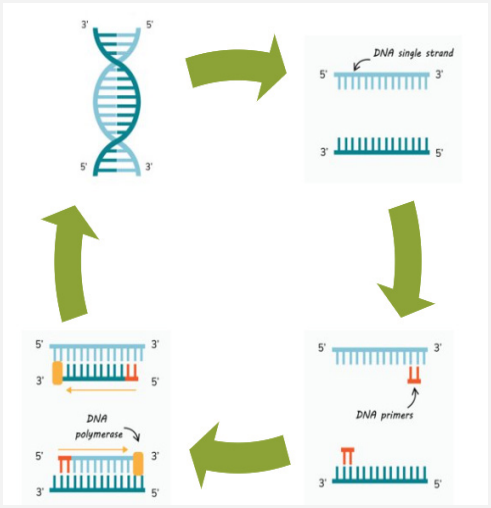

Figure. Principle of PCR analysis: selective amplification of allergen-specific DNA sequences enables identification of ingredient origin, even in processed foods.

PCR is also valuable when distinguishing between closely related sources, such as identifying the cereal origin of gluten. Under carefully designed conditions, PCR can also detect multiple allergens in a single analysis by combining several primer pairs.

However, PCR detects genetic material, not the allergenic proteins themselves. Translating DNA quantities into protein concentrations involves assumptions that introduce uncertainty. This makes PCR results inherently semi-quantitative.

PCR is therefore best suited for specific questions, such as confirmation of ingredient presence or species identification, rather than precise quantification of allergenic proteins.

LC-MS/MS – confirmation through protein fragments

Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS) is an emerging technique in allergen analysis. Instead of targeting intact proteins, this method analyses specific peptides derived from allergenic proteins.

This makes it more tolerant to processing and allows for highly selective detection. LC-MS/MS also offers the possibility to analyse multiple allergens simultaneously within a single analysis.

The challenge that comes with this technique is that it requires complex sample preparation, expensive equipment and specialised expertise. For this reason, it is currently mainly used as a confirmatory method rather than for routine testing.

4. From analysis to action: making results meaningful

One of the most challenging aspects of allergen analysis is accepting that different methods — or even different kits using the same method — can yield different results. This does not necessarily mean that one result is right and the other is wrong. More often, it reflects differences in targets, references and analytical principles.

A well-known example is soy lecithin: highly refined products may contain DNA but no detectable protein. PCR may therefore be positive, while ELISA and LC-MS/MS remain negative. Without understanding the analytical background, such results can easily be misinterpreted.

For QA teams, this highlights the importance of consistency and context. Comparing results from different laboratories or switching methods without understanding the consequences can easily lead to confusion. In many cases, methodological consistency is more valuable than pursuing a single "absolute" concentration.

This is where the role of the laboratory evolves from service provider to partner. Meaningful allergen analysis requires dialogue: discussing products, processes and risks before selecting the most appropriate analytical approach.

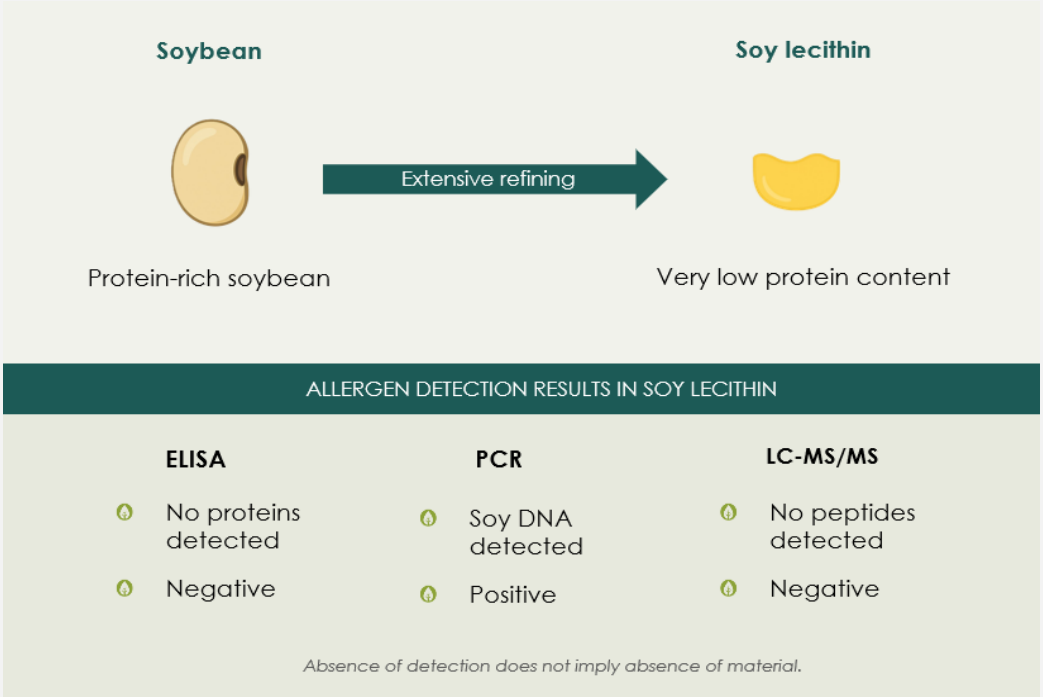

Figure. Impact of processing on allergen detection in soy lecithin using different analytical methods.

Conclusion

Allergen analysis plays a crucial role in protecting consumers and supporting food safety. At the same time, it is a field where simplicity is often misleading. There is no universal method, no single number that tells the full story and no one-size-fits-all approach.

The key to meaningful allergen analysis lies in asking the right question first, selecting the method that best fits that question, and interpreting results within their proper context. When this approach is followed, allergen analysis becomes not just a compliance exercise, but a valuable tool for informed decision-making.

At Primoris, we believe that reliable results start with understanding. By combining analytical expertise with practical insight into food production, we support our partners interpreting allergen results correctly and apply them meaningfully within their specific context.

You can rely on us

This information sheet provides a concise overview of key considerations in allergen analysis and method selection. If you would like to learn more about this topic and the analyses we offer, please do not hesitate to contact our customer care service.

- hello@primoris-lab.com
- +32 (0)9 330 10 13

Quality and reliability of our analyses is key to us, which is why our in-house R&D team is continuously working to improve our existing methods as well as developing new relevant methods based on market trends. Furthermore, our pesticide analyses are **BELAC 057-TEST** accredited conform the requirements of the EN **ISO/IEC 17025:2017** standard. In addition, we have **various recognitions** to further ensure the quality and relevance of our analysis scope. Below just a selection of our current recognitions.

relana®

Bundesverband Naturkost Naturwaren e. V.

GMP+ Feed Safety Assurance

QS-approved laboratory