PRODUCT INFORMATION

Allergens in food

Reliable analysis, correct labelling and sensible risk management

The European Food Information Regulation covers the mandatory allergen labelling of the 14 most common food allergens or groups of allergens. With two exceptions, no maximum residue limits are set for the allergens, which means that a „zero tolerance“ applies. For food allergy sufferers, this is not always a practical solution, as manufacturers protect themselves by stating „may contain traces of ...“. However, mandatory allergen labelling is only required if the food contains the allergen as an ingredient, component of ingredients (e.g. spice mixtures) or as an auxiliary substance (e.g. sulphite). If a substance loses its allergenic effect during processing, a declaration is not necessary (e.g. fully refined soybean oil, see Annex II of the Regulation[1]).

WHAT IS THE MEANING OF „GLUTEN-FREE“ AND „LACTOSE-FREE“?

Food allergies must be distinguished from intolerances. In an allergic person, even small traces of the allergen can lead to an overreaction of the immune system, such as anaphylactic shock. With intolerance, on the other hand, small amounts are still . However, labels such as „gluten-free“ and „lactose-free“ are misleading for consumers. Food may be labelled „gluten-free“ if it contains less than 20 mg/kg of the gluten protein. A claim as a product „with very low gluten content“ may be made for foods with a gluten content of more than 20 mg/kg up to a maximum of 100 mg/kg.

The use of the term „lactose-free“ is not regulated by law. Here, the consumer‘s perception associated with the label is the deciding factor. The position paper of the German Chemical Society (GDCh) from 2018[2] can be used to clarify the consumer‘s perception.

ALLERGEN MANAGEMENT IN FOOD OPERATIONS

In order to produce safe food, risk management is required, which starts with the selection of raw materials, monitors the production processes and even intervenes in the product design. Trade standards such as IFS Standard V.7[3] provide recommendations and requirements for effective allergen management.

A risk analysis is very complex and specific to each company. When changes are made in the manufacturing process from material purchasing to production, allergen management must always be taken into account, the risk assessment critically questioned and analysis plans dynamically adapted.

For contamination inspection at critical points and for checking the effectiveness of cleaning procedures, sampling of surfaces by means of swabs or sponges can be used in analogy to microbiological hygiene tests. Correctly performed sampling by trained staff is essential.

Likewise, rinsing solutions should be tested for allergens and results documented in order to obtain an assessment of the effectiveness of the cleaning protocol. Testing of other potential sources of allergens such as raw materials, additives and auxiliary materials (and possibly also packaging materials) is recommended at least on a random basis and when changing suppliers.

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The end product control ensures the assured specifications at the time of delivery to the trade. For this purpose, retained samples (at least beginning / middle / end) of a production batch should be taken for later checks.

Despite all precautionary measures, allergen transfer can occur unintentionally during the packaging of different products on a production line. In such cases, the only thing that helps the entrepreneur out of the product liability trap is the aforementioned notice „May contain traces of ...“ and usually leaves the allergen sufferer at a loss.

WHAT ANALYTICAL TOOLS ARE AVAILABLE?

A distinction is made between direct quantitative allergen determination methods and indirect detection methods, which generally only allow qualitative statements.

ELISA method (Enzyme-linked Immunosorbent Assay) - direct quantitative detection

Using a specific antibody, we capture the allergen from the sample and bind it to the surface of a well on a so-called microtitre plate. A second antibody, to which an enzyme is coupled, attaches to the fixed allergen molecule. If a special substrate is added, a photometrically measurable reaction product is formed. The allergen concentration is then determined via a calibration curve.

Specific antibodies cannot always be generated against food allergens. Both cross-reactivities and a change in the allergenic proteins during production can lead to altered detection behaviour.

Real-time PCR – indirect detection

In such cases, indirect detection is used, in which traces of characteristic species DNA can be detected in the sample. After isolation of the total DNA, the DNA sequence characteristic for the respective allergenic ingredient can be amplified in a real-time PCR (polymerase chain reaction) and made visible with specific fluorescence probes. If this characteristic DNA is detected, the probability is high that the corresponding allergen is also present in the sample. Advantage: If several characteristic DNA sequences of allergenic components are to be detected in one product, a more cost-effective multiplex PCR can be used.

PCR detection not suitable for egg and milk

The PCR method cannot be used for the detection of egg and milk components. In this case, it is not specific enough and would show a positive result even with corresponding meat components.

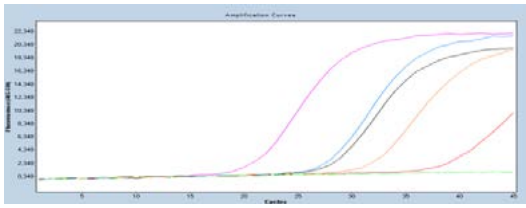
OTHER FOOD ALLERGENS

Lactose and sulphur dioxide/sulphite are no proteins, but are nevertheless allergens or can lead to intolerances. Their determination is carried out by means of ion chromatography (IC), liquid chromatographic separation with mass spectroscopic detection (LC-MS) or classical chemical methods.

Research has been going on for some time on a multi-method for the determination of the most important allergens in a single analysis, but so far no really robust method has been presented that could replace the currently established methods on an equal basis.

DETECTION LIMIT

All methods have a detection limit (and limit of quantification) that is in principle always greater than zero. Thus, a 100% absence of an allergen in a sample can never be confirmed analytically.



Comparison of ELISA and PCR

The applicability of the two technologies in processed foods also depends on the stability of the respective protein under the processing conditions. While in heated foods the target proteins sought may already be denatured, DNA as a target is stable for a longer time even at higher temperatures and PCR is preferable to ELISA. Conversely, nucleic acids in foods with low pH, e.g. pickled vegetables, are degraded more quickly than some proteins, which favours the use of an ELISA method.

Both methods are established standard procedures in routine use and are largely comparable in terms of sensitivity.

For some allergens it has therefore proven useful in practice to use a combination of ELISA- and PCR-based methods for the mutual confirmation of results.

YOR PLUS:

AGROLAB offers the detection of all 14 allergens listed in the EU by accredited and recognised allergen assays in raw materials, food and food supplements and also in pet food. We offer a detailed description of the performance characteristics of the methods used in an individual consultation, taking into account your products and manufacturing practices.

ALLERGENS SUBJECT TO OBLIGATORY LABELLING ACCORDING TO REGULATION (EU) 1169/2011 AND THE AGROLAB TEST SPECTRUM

		ELISA	PCR
Cereals containing gluten*	Gluten*/Gliadin* (e. g. from spelt, barley, oats, kamut, rye, wheat and hybrids)	✓	
Nuts*	Cashew	✓	✓
	Hazelnut	✓	✓
	Macadamia nut	✓	✓
	Almond	✓	✓
	Brazil nut	(✓)	✓
	Pecan nut	(✓)	✓
	Pistachio	✓	✓
	Walnut	✓	✓
Legumes	Peanut*	✓	✓
	Lupine*	✓	✓
	Soy*	✓	✓
Animal allergens	Egg*	✓	
	Milk*	✓	
	Casein	✓	
	ß-Lactoglobulin	✓	
	Lactose	IC or LC-MS	
	Fish*		✓
	Histamine	✓	
	Crustaceans*	✓	✓
	Molluscs*		✓
Spices	Mustard*	✓	✓
	Celery*		✓
Oil seeds	Sesame*	✓	✓
Preservatives	Sulfur dioxide* and sulfites	classic chemical analysis	

(✓) Introduction in preparation 2022

* Allergens covered by regulation (EU) 1169/2011

1) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32011R1169&from=de

2) Lebensmittelchemische Gesellschaft Fachgruppe in der Gesellschaft Deutscher Chemiker Positionspapier zu den Angaben „laktosefrei“ und „galaktosefrei“ August 2018
https://www.gdch.de/fileadmin/downloads/Netzwerk_und_Strukturen/Fachgruppen/Lebensmittelchemiker/Arbeitsgruppen/fde/laktosefrei_08_2018.pdf

3) International Food Standard v7 (Kapitel: 4.19 Allergen risk mitigation)
https://www.ifs-certification.com/index.php/en/standards/4128-ifs-food-standard-en