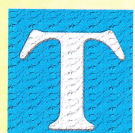


Assessment of allergenic traces – still a major challenge



The EU regulation 1169/2011 lists 14 food allergens, which have to be labeled if they are used as ingredients. The problem is not the declaration of ingredients, but unexpected hidden traces of allergens. According to many food producers mainly raw materials are affected.

The EU has one of the highest food safety standards in the world. A key tool to ensure the cross-border exchange of information to swiftly react in the food chain is RASFF - the Rapid Alert System for Food and Feed. The RASFF annual report 2015¹ shows after a long time of stabilising figures a substantial increase of notifications reported on allergens in 2015. Although there was a particular case regarding almond allergen in this year an increase of notifications could be observed for quite a number of allergens (e.g. milk ingredients, undeclared sulphite, egg, peanut, soya, gluten).

Especially raw materials like spices can contain unexpected contaminations and thus being a high potential risk for consumers suffering from food



mixtures were reported (3, 3.3 and 19 mg /kg almond) and traced back via a Swedish operator to a Spanish paprika powder producer. Another alert was a recall of ground cumin with undeclared almond levels up to 306 mg/kg. The ground cumin of Turkish origin was analysed both by ELISA and PCR analysis and returned an ELISA positive and a PCR negative result. It was shown that the ELISA generated a false positive result due to the addition of *Prunus mahaleb*, because the ELISA test showed cross-reactivity to this species. In March recalls of products due to traces of almond in

almond shells as an ingredient in paprika powder. Spanish authorities communicated with regards to the second Spanish paprika producer that according to Article 13(2) of Royal Decree No 2242/1984 the use of almond shell flour as a spice substitute is authorized¹. However, as almond is listed in the EU regulation 1169/2011 as a food allergen it has to be indicated on the label if it is used as an ingredient.

First these notifications indicate the importance of careful sourcing of raw materials in the food industry. Secondly, it underlines the necessity of highly specific and sensitive analysis methods for allergens. Another issue is the importance of quantitative analysing methods. Currently two techniques are commonly used and widely accepted for allergen analysis: protein based ELISA or DNA based PCR. Both methods can be used to generate quantitative results. Depending on the matrix, processing and type of allergen the analysing method must be chosen.

Quantitative PCR methods using a laboratory reference material for quantification are available for many food allergens. The advantage in comparison to other technologies is the use of an external standard based on a food matrix minimizing differences in matrix effects. SureFood® QUANTARD Allergen 40 (R-Biopharm AG) for example is a laboratory reference material based on corn flour containing food allergens in a defined amount of 40 mg/kg (e.g. 40 mg raw almond nut in 1 kg corn flour matrix). CONGEN Biotechnology GmbH has been using this material for quantifying traces of allergens up to 400 mg /kg for already six years in the food service lab. In 2015 and 2016 we have received several cumin samples, which were analysed for different allergens with real-time PCR. (See table 1). In some cases contaminations > 400 mg/kg of the respective allergens were found.



allergies. For example garlic from China is flavoured with peanut. Garlic powder from China often shows contaminations with peanut between 10-50 mg/kg (ppm). There are also regional differences with respect to food allergies: In China only a few people suffer from peanut allergy whereas in Europe many peanut allergic people react to even very small traces of peanut.

In 2015 there were a number of food recalls in the US and Canada due to undeclared traces of peanut and almond in ground cumin. In February another three cases on undeclared almond in spice

spices were observed in Belgium and Denmark. After retracing both alerts could be related to two different Spanish paprika producers. At this point, serious doubts were voiced by the industry over the reliability of the analyses. Tracing back the first case, it was shown that one paprika producer used

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Labeling of food products

The current EU regulation 1169/2011 defines no threshold/action levels for the labeling of food allergens. Moreover there is no rule for the handling of allergenic food residues due to cross contaminations or missing labeling of raw materials. That poses a high risk to food-allergic individuals. The food industry voluntarily applied precautionary allergen labeling statements like "may contain..." to food products. Due to over-use of precautionary allergen labeling consumers are frustrated or even ignore these statements.

To improve the use of the "may contain" labeling the Allergen Bureau of Australia & New Zealand established the VITAL (voluntary incidental trace allergen labeling) concept. In 2010 a revised version VITAL 2.0 was introduced using published and unpublished clinical data to generate reference doses (mg protein) for many food allergens. The dose of allergenic food depends on the concentration of the allergenic food residues

Table 2: Calculation of peanut amount in a sample

Sample amount	340	g =	0,34	kg
Peanut amount in the sample	189	mg/kg		
	64.26	mg/	0.34	kg

in the food product and the amount of the particular food that is consumed. That means foods typically consumed in small amounts would result in lower doses whereas foods consumed in larger amounts will result in higher doses. For example peanut has a VITAL reference dose of 0.2 mg protein². VITAL also provides a guideline to convert from protein to food. As the protein content for peanut is 25% it is equal to 0.8 mg food².

To give an example we analysed a sample of vegetarian spread with pepper and cheese and found 189 mg/kg peanut in two glasses of 170 g.

That means 2 glasses of the vegetarian spread (each 170 g) containing 64 mg peanut, which is much higher than the limit of 0.8 mg according to the VITAL grid.

References:

- 1 https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2015.pdf
- 2 S.L. Taylor et al. /Food and Chemical Toxicology 63 (2014) 9-17

New study Finds EPA and DHA omega-3s lower risk of coronary heart disease

EPA and DHA omega-3s reduce the risk of coronary heart disease (CHD), according to results of a new, comprehensive meta-analysis published in the Mayo Clinic Proceedings and sponsored by the Global Organization for EPA and DHA Omega-3s (GOED). Among randomized controlled trials (RCTs), there was a statistically significant reduction in CHD risk in higher risk populations, including:

- 16% in those with high triglycerides and 14% in those with high LDL cholesterol.
- A non-statistically significant 6 percent risk reduction among all populations in RCTs, a finding supported by a statistically significant 18% reduced risk of CHD among prospective cohort studies.

"What makes this paper unique is that it looked at the effects of EPA and DHA on coronary heart disease specifically, which is an important nuance considering coronary heart disease accounts for half of all cardiovascular deaths in the U.S.," said Dr. Dominik Alexander, lead author and Principal Epidemiologist for EpidStat. "The 6 percent reduced risk among RCTs, coupled with an 18% risk reduction in prospective cohort studies – which tend to include more real-life dietary scenarios over longer periods – tell a compelling story about the importance of EPA and DHA omega-3s for cardiovascular health."

Additional study details include:

- The study reviewed 18 randomized controlled trials (RCTs) and 16 prospective cohort studies, with 93,000 and 732,000 subjects, respectively.
- The study examined outcomes such as myocardial infarction, sudden cardiac death and coronary death.
- The study compared the results of RCTs, which explore interventions under strict clinical conditions, to those of prospective cohort studies that are observational, and followed larger populations for longer periods of time.

"There are important public health implications related to reducing the risk of coronary heart disease, and therefore we are encouraged by the results of this comprehensive analysis," said Dr. Harry Rice, Vice President of Regulatory and Scientific Affairs for GOED. "It's also important that the observed risk reductions were even stronger in

patient populations with elevated triglycerides and LDL cholesterol levels, two risk factors that affect more than one quarter of the American population."

"The results confirm that increasing omega-3s is a healthy lifestyle intervention that can contribute towards reductions in CHD risk," added Adam Ismail, Executive Director of GOED. "Remember that increasing omega-3 intakes is basically just improving the quality of one's diet slightly, like reducing the amount of sodium or increasing your dietary fiber. It is a simple, inexpensive, and achievable change that most consumers need to make to optimize their health."

An accompanying editorial in Mayo Clinic Proceedings also acknowledges the importance of the study. "The meta-analyses of Alexander and colleagues suggests that omega-3 fatty acid intake may reduce risk of adverse CHD events, especially among people with elevated levels of TGs or LDLc....omega-3 fatty acid intake of at least 1 gram of EPA+DHA per day, either from seafood or supplementation (as recommended by the American Heart Association), continues to be a reasonable strategy," said the authors.

Study authors did point out that further clinical trials looking specifically at CHD outcomes may continue to provide a better understanding of the promising beneficial relationship between EPA/DHA and CHD risk. Current RCTs have varying durations, different baseline CHD status for study participants, and utilize several methods for patient selection and randomization.

Future studies should:

- Increase patient populations to account for dropout rates in longer trials.
- Extensively detail how subjects are diagnosed to create uniform diagnostic criteria.
- Be appropriately powered to detect an effect in current clinical conditions.
- Measure baseline omega-3 intake or status of study participants to determine the extent to which it confounds results.

The study was supported by a grant from GOED, which played no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

Barry Callebaut completes acquisition of chocolate production facility in Halle, Belgium

Barry Callebaut AG, the world's leading manufacturer of high-quality chocolate and cocoa products, successfully closed the acquisition of the chocolate production facility from Mondelēz International in Halle, Belgium, as announced on September 15, 2016. This follows the completion of works council consultations and closing conditions. The factory in Halle, which will be integrated into Barry Callebaut's global manufacturing network as of January 1, 2017, will expand the company's production capacity for quality Belgian chocolate and fillings. The transaction also includes a long-term agreement for the supply of an additional 30,000 tonnes of liquid chocolate per year to Mondelēz International, which will start in early 2017.

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