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Editorial Comment

Learn from the past... Improve for the future!

Another year is coming to an end. Now it's time to look back to evaluate and summarize the achievements, areas for improvement and trending topics that we would like to address in the new year. Although there have not been major developments in the regulatory arena, the US FDA is considering introducing sesame seeds as additional allergen requiring labeling. Bert Popping discusses this news in his article raising the question around the fact that the Codex Big 8 may soon require a redefinition, as has happened with the "kilogram". In this issue of the newsletter, Richard Fielder writes about the update of the "kilogram" reference and what it means for test kit manufacturers. In connection with accuracy of measurements, and after years of inactivity, the development of food allergens reference materials is becoming a hot topic. In previous issues we have communicated the activities of MoniQA Association in this regard. In this issue, colleagues from the National Institute of Standards and Technology (NIST) describe their current efforts in this area.

Along the year we have also had opportunities to meet colleagues and discuss new developments on food allergen and gluten testing in various events, including the 2nd ICFA and the AOAC Annual Meeting in Toronto.

The Food Allergen Community co-chairs, Jupiter Yeung and Carmen Diaz-Amigo, wish you all a Merry Christmas. We look forward to the new year, in which we will keep working on providing a networking ground to exchange information and to promote collaboration efforts.

Carmen Diaz-Amigo [in](#) Editor in Chief

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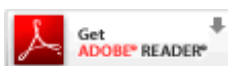
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Featured Article

Big 8 or Big 9? Will the US FDA add Sesame to its Allergen List?

Currently Europe, Canada and Australia/New Zealand require the labelling of sesame as food allergen. Japan has added sesame in 2013 to the list of 20 allergens which are recommended to be labelled (but are not mandatory at this point).

In Europe, lawmakers required **sesame labelling** already in 2003, jointly with 11 other substances causing food allergies or intolerances. In 2014, the European Food Safety Authority (EFSA) updated its opinion of allergenic foods and food ingredients for labelling purposes. For sesame, it stated that the highest prevalence in Europe is 1.5 % in France among 5-17 year-old individuals. While information about documented severe reaction was scarce, a questionnaire suggested that sesame was responsible for severe reactions.

What are the reasons of FDA to consider now adding sesame to the list of allergens requiring labelling?

In a **statement of departing FDA Commissioner Scott Gottlieb** on Oct 29, 2018, he mentions that "Unfortunately, we're beginning to see evidence that sesame allergies may be a growing concern in the U.S. A handful of studies, for example, suggest that the prevalence of sesame allergies in the U.S. is more than 0.1 percent, on par with allergies to soy and fish. Because sesame is not recognized as a major allergen, right now it's not required to be declared as an allergen on food labels. In fact, it may not always be specifically listed in the ingredient statement. Products with "natural flavors" or "spices" listed on their label may contain small amounts of sesame. And people allergic to sesame might eat food labeled as containing "tahini" without knowing that tahini is a paste made from sesame seeds. Fear of not knowing whether a food contains sesame may lead some people to unnecessarily limit their diets to avoid possible exposure."

As mentioned by **Harriet Moonesinghe and co-authors** in their 2015 review, very little data about the true prevalence of what the authors consider "novel" food allergens (celery, lupin, mustard and sesame) are available. So, if prevalence of sesame allergy is only 0.1% or higher in the US is unknown. The US FDA also recognized this and is therefore issued a **request for information**.

How many sesame allergens are there?

For sesame, there are seven characterized proteins which can trigger the allergy reaction. These fall into three protein



Photo by Arzamasova

families: two prolamins (Ses i1 and i2), two oleosins (Ses i4 and i4) and three cupins (Ses i3, i6 and i7).

Are sesame allergens heat stable?

This information is essential for food manufacturers using sesame in baked products. The answer is: yes. The major Sesame allergen, Ses i1, is stable up to 90° C. Ses i1 is also highly resistant to digestion in the gastrointestinal tract which is common to many food allergens.

VITAL reference dose and enforcement levels for sesame

For sesame, the VITAL reference dose for sesame protein is set at 0.2 mg, with an ED05. In Germany, the VITAL reference dose has been adopted and the action level is set to >10mg/kg, meaning that if the competent authorities find more than 10 mg/kg (or 10 ppm), they will take action.

In the neighbouring countries, The Netherlands propose a significantly lower reference dose of 0.1 mg sesame protein, while Belgium, the other neighbouring country set a substantially higher reference dose of 0.4 mg sesame protein. In other words, if you live in Belgium, 400 g of a dish can contain a maximum of 1 mg/kg sesame protein, while in Holland, the same dish could only contain 0.25 mg/kg sesame protein to reach the reference dose in the respective country. However, analytically, 0.25 mg/kg sesame protein may not be detectable by most commercial assays.

Detection of sesame

Commercial ELISA (Enzyme-Linked Immuno-Sorbent Assay) systems for sesame are available from many vendors. Equally,

DNA-based systems (PCR – Polymerase Chain Reaction) are also described in the literature and available commercially. More recently, mass spectrometry methods for detection of sesame have been published, too.

Prevalence of Sensitization and Prevalence of Sesame Allergy in different Countries

According to the EFSA report (2014), sesame allergy is comparably rare (averaged about 0.1% compared to 1% for peanuts and tree nuts – this percentage varies from region to region). However, children sensitized to sesame had a high prevalence of sensitization to peanuts, hazelnut, walnut, almond, and egg. Both, cross-sensitivity and clinical cross-reactivity, were observed between sesame, peanut and tree nuts

The prevalence of sesame allergy is subject to significant geographical variation. In the Middle East, popular dishes like tahini and halva contain sesame, and it was assumed that, based on the higher consumption rates of sesame in those regions, the prevalence of sesame allergy was high. Sesame was already termed “**peanut of the Middle East**”. The assumed

higher prevalence in the Middle East was supported by Israeli studies with small groups. However, those studies were not population-based. A higher prevalence is reported from Australia (0.8%) and UK (0.4%).

As mentioned previously, there are still very little data available to determine the true prevalence of “novel” food allergens like celery, lupin, mustard and sesame. **Harriet Moonesinghe** and co-authors come in their 2015 review to the conclusion: “There is surprisingly little data available on the prevalence of these novel food allergens despite the fact that they appear in the top 14 food allergens listed by the EU.”

It remains to be seen how much reliable evidence can be gathered through the FDA call for information to support the assumption that the prevalence of sesame allergy in the USA is higher than 0.1%. Given that the prevalence of sesame is likely significantly lower than those for peanut and tree nuts, will sesame be the 9th mandated allergen in the US?

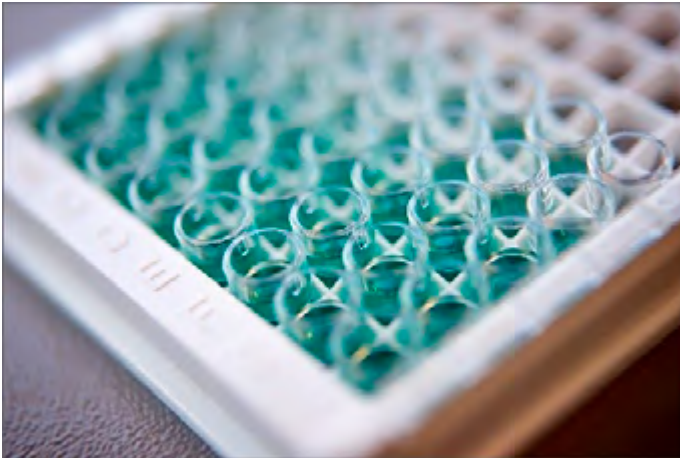
Bert Popping  FOCOS GbR

*The Food Allergen Community
wishes you a
Merry Christmas*



News

After a Long Wait, There's No Longer a Weight. A Test Kit Manufacturers Perspective



Background: All good things are worth the wait and the weight we lose is strictly speaking a mass ... On the 16th November, the world's increasing demands on measurement, lead to the redefinition of the kilogram (BIPM, 2018). As one of the seven SI base units of quantities (which are used for defining 22 derived units in this internationally agreed system organised by BIPM), the kilogram for mass is now defined in terms of an electric current rather than a physical object - the platinum-iridium ingot held in Paris called "Le Grand K". After almost 130 years, Le Grand K, as well as six copies held around the world, have been deteriorating with discrepancies between them. The new definition is based on a constant of nature, Planck's constant, which is more robust and will lead to more precise measurements (Horizon, 2014).

What does it mean for allergen analyses? For all types of measurements this is an important moment, including for the measurement of the allergen content in foods. A key challenge for robust allergen analysis is the ability to relate results back to a reference. For there to be this essential metrological traceability there needs to be a documented unbroken chain of calibrations, each contributing to the measurement of uncertainty (VIM, 2012), linking back to the reference – in this case, the kilogram, the SI unit of mass.

The benefit of metrological traceability is confidence in the measurement result. This in turn leads to confidence in the implications of the measurement, which for allergen analyses includes: the effectiveness of allergen controls, the

levels of cross-contact, the allergen content of a finished product, compliance with a regulatory threshold for gluten. Consequently, this could lead to improvements, for example, in: mandatory & precautionary allergen labelling, allergen information in food service operations, best practice and better protection for the allergic consumer.

The way forward Currently, when accredited laboratories (ISO17025) perform analyses of a homogenous sample in a proficiency testing round and use different ELISA test kits, submitted results differ. The lack of metrological traceability inherent in the analyses leads to reduced confidence in the accuracy of the results and predictions made from them. The work necessary to address these urgent analytical needs has already been critically reviewed (Walker et al., 2015). The review identified three gaps (production of reference materials, a bioinformatics gap analysis and the development of reference methods) which need to be addressed by the co-ordinated efforts of the allergen analytical community - in particular, through the National Measurement Institutes (e.g. Joint Research Centre of the European Commission) and international collaborations (e.g. MoniQA). These gaps also impact the current work of those involved in standardisation, especially now that there are partnership agreements in place between AOAC/ISO and ISO/CEN. For example, CEN/TC 275/WG12 on Food Allergens is revising technical standards that will provide general considerations and minimum performance criteria for different types of allergen and gluten methods. All these efforts, will help to ensure that different methods produce reliable, repeatable and comparable measurement results. Yet to compare results, the units of measurement need to be reported in the same way, preferably expressing the allergenic ingredient protein content and/or by providing a conversion factor. As we approach 2019, there needs to be a greater move to adopt SI units which should mean avoiding the use of 'parts per million'; instead expressing results for example as 'mg gluten / kg of food' or a 'gluten content of 20 mg/kg food'.

Useful source: www.bipm.org

Richard Fielder | Bio-Check (UK)

Food Allergens at the National Institute of Standards and Technology (NIST)

Food allergen management is an increasingly important public health and economic concern; accurate and reliable allergen measurements are a crucial component of the management pathway. Traditional methods for food allergen detection are based on immunoassay techniques and are linked to a specific commodity (e.g., total milk protein, total egg protein). However, the emergence of mass spectrometry-based platforms has revealed the need for reference materials that support protein-specific measurements. To support the harmonization of food allergen measurements, the new food allergen research effort at the U.S. National Institute of Standards and Technology (NIST) is focused on providing reference materials and methods to improve the connection between the measured protein food allergen and the reported total commodity value. Food allergens is one of several target areas of a larger food safety program at NIST to identify the measurement needs within the food allergen management community.

Current food allergen reference materials include a value for total commodity as determined by non-specific approaches, such as total nitrogen measurement, and contain no direct link between the measured food allergen protein(s) and the reported total commodity value. Approximately 18 NIST food reference materials are available that include a reference value for total protein as determined by conversion from a total nitrogen measurement, which potentially could be used to support food allergen measurements. Consequently, claims of traceability for measurement of a specific protein allergen, such as measurements determined by mass spectrometry, to the results of a total nitrogen measurement are invalid. Therefore, adding values for the mass concentrations of specific protein food allergens or their surrogates in existing NIST food reference materials will improve the degree of measurement traceability and provide tools for the user community to validate food protein allergen measurements. In addition to expanding the use of existing reference materials,



NIST seeks to develop partnerships within the food allergen management community to develop new reference materials and methods that address present and future measurement needs. In an effort to identify measurement needs and guide the development of reference materials, NIST is organizing interlaboratory studies to assess measurement equivalence of milk proteins across multiple platforms for simple and complex food samples.

For more information, please contact Drs. Ashley Beasley Green (ashley.beasley@nist.gov), David Bunk (david.bunk@nist.gov), or Melissa Phillips (melissa.phillips@nist.gov).

Ashley Beasley-Green, David Bunk, Melissa Phillips
NIST

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Highlights of the 2nd International Conference on Food Analysis (ICFA)



The 2nd International Conference on Food Analysis (ICFA) 2018 was held in Melbourne from 20th – 22nd November 2018 in Melbourne, Australia (www.icfa2018.com.au). The event was successful on many levels, with approximately 140 delegates from 15 different countries attending the conference.

The 2nd ICFA delegates were welcomed by Mr. James Roberts, Honorary Fellow at the National Measurement Institute (NMI). The opening address was delivered by Prof. Simone Richter, Group Executive at the Nuclear Science and Technology and Landmark Infrastructure at the Australian Nuclear Science and Technology Organisation (ANSTO), highlighting the relevance of food and the accurate measurements of food products and the trust consumers have in the products. Plenary speaker Prof. Samuel Godefroy, University of Laval, presented on food fraud its long history and vast impact. Food fraud and food authenticity were discussed at different sessions at ICFA, with honey being the most discussed commodity. Plenary speaker Prof. Andreas Lopata, James Cook University, informed about the newest research for Asia-Pacific fish and shellfish allergy. Food allergen presentations included the tree nuts important to Australia, egg allergens, gluten detection and current surveys for undeclared allergens being conducted in Australia. Mr. Adrian Rogers, Romer Labs, informed about food allergen and food fraud incidences and court cases in the UK. Plenary speaker Dr. Michelangelo Anastassiades, EURL-SRM, discussed the measurements of pesticides. The Asia Pacific Food Analysis Network (APFAM) contributed to the ICFA conference. Other topics discussed at ICFA included foodborne pathogens (in particular viruses) and the difficulties of measurements in food products. Further topics included hemp foods, persistence

organic pollutants (including PFOS/PFOA), vitamin D and proficiency testing.

Prior to the ICFA, on Monday 19th November 2018 the Allergen Testing Special Interest Group (AT-SIG) meeting was held at the same venue. The AT-SIG meeting was organised by the NMI and the Allergen Bureau. 50 delegates were welcomed by Dean Clarke from the NMI. The Allergen Bureau, Food Standards Australia and New Zealand, R-Biopharm, Romer Labs and ELISA Systems presented updates and current activities. Fiona Jones from the Department of Health and Human Services explained the new mandatory reporting legislation in regards to Hospital Notifications of Anaphylaxis in Victoria. Adrian Rogers gave insights to Personal Detection Systems for food allergens. Jason Tye-Din shared the medical perspective about gluten testing at the AT-SIG meeting and at ICFA the controversies of a gluten-free diet. Researchers at the Murdoch Children's Research Institute gave the clinical perspective on food allergens at ICFA and AT-SIG. Martina Koeberl spoke about the difficulties of food allergen testing at ICFA and AT-SIG. James Roberts summarised recent food allergen incidences. Joanne Price and Peter Bush shared their experience on food allergen management from a (SME) manufacture and industry perspective. Robin Sherlock closed the AT-SIG meeting.

The next ICFA will be held in Melbourne in November 2020. The ICFA organising committee is looking forward to welcoming all.

Martina Koeberl
Australian National Measurement Institute



Keerati / freedigitalphotos.net

Guest Editor Special Section of the Journal of AOAC International on Food Allergens

All 25 manuscripts are open source, meaning that you can download them free of charge.

Upcoming Events

2nd International Conference of the Food Allergy Forum

April 1-3, 2019
Amsterdam, The Netherlands

The main objectives of the Food Allergy Forum are: providing a unique platform to exchange information and experiences on the various aspects of food allergy; reviewing current knowledge related to food allergy; and discussing strategies for prevention and control of food allergy ensuring food safety and protecting human health.

AOAC Food Allergen Community Newsletter

Contribute with articles, news items or suggestions.

Submission deadline for the 1st issue of 2019: **March 29**

Send your articles to AOAC.Allergens@gmail.com

Topics for publication

- ✓ Regulatory Updates
- ✓ Food Industry Initiatives
- ✓ Regional developments
- ✓ Your research
- ✓ Upcoming events
- ✓ Questions for our Experts
- ✓ Interested in a topic?

Article requirements*

- ✓ Short title
- ✓ Length: 400 words max.
- ✓ 1 figure or table (optional)
- ✓ Author & Affiliation
- ✓ Related links
- ✓ No advertising

* All articles are subject to review by the Editorial Board.



The AOAC Food Allergen Community is a forum serving the scientific community working on Food Allergens: The community aims to help AOAC INTERNATIONAL in its consensus-based scientific and advisory capacity on methods of analysis for allergens in foods and other commodities. It is also meant to serve the broader Stakeholder Community whose objectives it is to enhance the protection of food allergic consumers worldwide.

Contact us at
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