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## Editorial Comment

### Shore Ahead!

It must have felt similar when the Mayflower reached the American coast after 66 days on sea. After 30+ years of food allergen testing, we are seeing some of the crucial needs starting to be covered. Carmen Diaz-Amigo reports in her feature article that many allergen conference and meeting she attended had three questions in common: do we have a confirmatory method; do we have a reference material; and do we have a threshold? Her article shares the recent developments towards meeting those needs. And by now, even Codex Alimentarius has, led by USA and Australia, started to produce an allergen Code of Practise (CoP). It will be interesting to see if these recommendations are in line with existing private standards requirements. The first draft of the CoP is in circulation for commenting until October 15th. And it appears Australia is leap-frogging ahead when it comes to food allergens: FSANZ has created a Food Allergen Portal. There is also some news on the Gluten front: Roland Poms of MoniQA reports about improved reference material for gluten analysis, a consensus-based material which will become commercially available by end of this year.

The interest in food allergens is not waning as seen by the download numbers of the articles in the Special Section on Food Allergens, published in January. The editorial board of the Journal of AOAC International shared these number in the latest edition of ILM: the special section manuscripts achieved the highest download frequency in the recent history of the journal. Congratulation to the authors and contributors! Last but not least, the AOAC Annual Meeting is around the corner (time-wise, not geographically since many of us will have to travel from overseas), where The Food Allergen Community will meet once again. Moreover, there will be three sessions on food allergens. We hope to see you again!

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

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## Featured Article

### Reflection on 20 Years of Food Allergen Testing

It has been almost 20 years when my professional career took a 180-degree turn and I moved from the small molecule world of mycotoxins to the large and complex compound world of food allergens and gluten. I found that new start was challenging given the number of unknowns and questions that needed answers. But most of all, I found food allergens an exciting field to contribute to.

At that time, beginning of the 21st century, we lived with the Big 8 food allergens defined by Codex and with the 200 ppm of gluten threshold for labeling products as gluten-free. Today, many jurisdictions have enacted food allergen labeling regulations, most of them based on the Codex Big 8 (USA), many have expanded this list over time (EU, Canada, Australia), and some have deviated from Codex and adjusted the regulated food allergen labeling considering the local food allergy prevalence (Japan).

Back then we could only find a handful of ELISA assays in the market for a few food allergens, mainly peanuts, milk, egg and gluten. Now, it is difficult to keep track of all allergen assays available in the market. We have more analytical technologies available, not only immunoassays but also PCR and mass spectrometry, which allow us to detect all mandated food allergens, although with some question marks in some instances, e.g. the ability to detect all fish and crustacea species. All analytical technologies have their particularities, pros and cons, they all share common challenges as there are also technology-specific challenges. They all have their own place in the testing market and in many cases, they have complementary roles.

In all these years we have learned that food processing activities have an important effect on food allergens, their extraction from samples and further detection by the different analytical applications. We know that not all food processes have the same impact on the food allergens and that not all food allergens are affected equally. And for these reasons food matrices determine our analytical strategies, including sample extraction methods and choice of analytical method.

I have never counted how many hours I've spent attending food allergen conferences, committees, working groups, task forces... quite a few. In those events, colleagues have shared information on research, new analytical developments, regulatory novelties, projects, industry initiatives, etc., but I have also heard the same questions over and over, like an echo that goes from meeting to meeting. I have selected 3 of those almost eternal questions/needs, that now (caution:



Photo by Louis Reed on Unsplash

spoiler) seem to get answers. Are those answers the ones we wanted to hear?

The first question was about the availability of confirmatory methods. The need was to find analytical technologies different than the existing immunoassays. This need found a first solution some years ago, with the application of DNA-based methods. However, this option has not been accepted as valid analytical option by some countries, e.g. United States and Australia/New Zealand, Canada, since they do not target the proteins (food allergens), which are the actual triggers of food allergies. More recently, new improvements in the mass spectrometry (MS) technology led to the development of applications for food allergen detection. Since then, I have not seen a single presentation asking for new confirmatory methods.

The second question is related to the need for reference materials for calibration, validation, quality control and to facilitate the comparison of analytical results given by different analytical methods. After many years of inactivity in this field, excluding the prolamin working group (PWG) gliadin, where the material is of limited availability, there has not been globally accepted reference materials for either food allergens or gluten testing. This has been the case until 4 or 5 years ago, when the MoniQA Association gathered stakeholders and started an initiative to identify, select, characterize and produce materials to be used across platforms (immunoassays, DNA-based assays and mass spectrometry). Milk is already available, and gluten will be shortly in the market. More recently, there are also new activities in this field, one in Europe sponsored by the Food Standard Agency in the UK and also in the US by the National Institute of Standards and Technology, and an additional one which is not yet in the public domain. So, it

seems that soon we will have more materials available. And then the question needs to be asked: are these materials equal or are some more equal than others?

The third point is the need for threshold levels. After the enactment of food allergen labeling regulations, we have seen an increase in the number of recalls due to presence or potential presence of food allergens. Many have pointed out that a possible reason is that the lack of regulated or recommended official threshold levels for food allergens pushes industry to manage allergens with zero-tolerance. This results in very costly controls that do not seem to bring additional protection or benefit for the consumer. Moreover, the lack of official threshold levels creates inconsistency across the industry in the manner they assess risk and control food allergens. If having threshold levels will contribute to the reduction in the number of recalls due to food allergens remains to be seen. Looking at recalls due to gluten (in the context of gluten-free labeling for celiac sufferers), where there is a threshold of 20 ppm gluten in most countries, the number of recalls remains high.

A first initiative to address allergen levels was led by the food industry in Australia, which is known as VITAL. This system is a risk assessment tool for the industry with associated reference doses for the mandated food allergens and used for labeling purposes. The establishment of these allergen levels has been based on the evaluation of scientific and clinical

information. Such levels have been suggested to government regulatory agencies, none has yet adopted them or made any recommendations. However, in the last couple of years there have been some activities in governments of 3 central European countries: Germany, Belgium and the Netherlands (**Food Allergen Community Newsletter 2018, vol 9, issue 1**). Although it seems a move forward, the levels are significantly different in the three countries. While in Germany, the values established have their base in findings from enforcement activities by control authorities, the Belgian values are based on VITAL and the Dutch values, the lowest of the 3 countries, are based on an own assessment. As we have seen in other areas, having diverse threshold/tolerance levels does not only create compliance complexity but is also unhelpful for affected consumers.

Although many efforts are driven to involve different stakeholders and provide consensus agreements positions and recommendations, not all activities have converged. The need to find practical solutions to chronic needs, e.g. reference materials and threshold levels, and the lack of a clear lead in these areas is steering some efforts in different directions. Given the proliferation of reference materials produced to different specifications, thresholds and action levels.... Do we need to start thinking about harmonization? Will it be the next hot topic that we will hear in all the meetings?

Carmen Diaz-Amigo  FOCOS GbR



## Most Downloaded Guest Editor Special Section of the Journal of AOAC International

In January 2018, the Journal of AOAC International published the Special Section on Food Allergens, a collection of manuscripts authored by globally recognized experts. Half a year later, the Editorial Board of the Journal of AOAC has shared with us that this has been the most downloaded special section recently. All 25 manuscripts are open source, meaning that you can download them free of charge.

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## News

### Codex Works on Allergen Code of Practise for Food Industry



It was in November 2017 at the Codex Committee on Food Hygiene when Australia and the United States proposed to develop a Code of Practice on Food Allergen Management for Food Business Operators. The purpose of this document was to provide guidance to both, food manufacturers as well as governments, to manage allergens in food production. Such guidance would include advice on avoidance of cross-contact and advice role of labelling, especially precautionary labelling.

#### Which types of allergies will the document address?

While often food allergy and food intolerance are used as synonymous, they are not the same. There are three main immune mechanism which can cause adverse health effects:

- immunoglobulin E (IgE)-mediated (the most typical food allergy immune reaction)
- non-IgE mediated (cell-mediated), and
- mixed IgE and non-IgE mediated

The scope of the document addresses measures that the industry can take to prevent all these three types of disorders.

#### What triggers Food Allergy Recalls?

Over the past years, jurisdictions regulating food allergens have seen an increasing number of products being recalled. In the United States, the number of food allergen-related recalls in 2016 was even higher than the number of spoilage/pathogen-related recalls. Australia performed an analysis of the causes for recalls between 2016 and 2017.

The most common reasons were:

- Lack of skills and knowledge of labelling requirements
- Supplier verification issues
- Packaging errors
- Accidental cross contact

#### Which Points will the Code of Practise Address?

- Definitions – what are food allergens requiring management and what is allergenic contamination (e.g., “cross-contact”).
- Role of competent authorities, food business operators and consumers – Enforcement agencies, food businesses and consumers all have a role in the risk management of food allergens. Understanding the nature of this issue, the appropriate control measures and the information needs of consumers, informs requirements for compliance and enforcement to deliver safe food outcomes.
- Training and supervision – best practice allergen management and awareness for employees.
- Raw materials – allergen management practices to minimise risk.
- Storage and distribution – identification and segregation of allergens.
- Manufacturing and food service – control measures, including equipment, process design and cleaning.
- Formulation and labelling – ensuring all allergens in the food are included on the label.
- Testing and analysis – validation and verification of allergen control.
- Risk management tools – Consumer complaints, corrective actions, recalls.

#### The Draft Version

Earlier this week, a draft document of the Code of Practise has been circulated for commenting. The draft consists of the following chapters:

- Primary Production
- Establishment – Design and Facilities
- Control of Operation
- Establishment – Maintenance and Sanitation
- Establishment – Personal Hygiene
- Transportation
- Consumer Awareness and Product Information
- Training

There are several points in the document which are under discussion, e.g. if dust can lead to cross-contamination.

Bert Popping [in](#) FOCOS GbR



## Useful Resources

### FSANZ Food Allergen Portal



### White Paper



### AOAC Food Allergen Community Meeting

Jupiter Yeung and Carmen Diaz-Amigo, co-chairs of the AOAC Food Allergen Community, cordially invite you to participate in the meeting that will take place during the AOAC Annual Meeting in Toronto:

Sheraton Centre Toronto Hotel  
**Tuesday, August 28, 4:45 pm – 6:45 pm**

#### AGENDA

- Welcome and self-introductions
- ISPAM activities - SMPR developments - Samuel Godefroy & Jupiter Yeung
- Threshold and Action levels in Europe - Bert Popping
- Community Updates
- Short Oral Presentations:
  - Developing Reference Materials for Protein Allergens in Food – David Bunk (NIST)
  - Challenges of MS-Based Methods for Allergenic Food Proteins - Ashley Beasley Green (NIST)
  - From Signal to Analytical Reporting for Allergen Detection by Mass Spectrometry - Philip Johnson (University of Nebraska)
- Additional business
- Adjourn

Additional food allergen-related activities that will take place during the AOAC Annual Meeting:

**Sunday, August 26, 8:30 am – 12:30 pm**

AOAC International Stakeholder Panel on Alternative Methods (ISPAM) Meeting. AGENDA

**Sunday, August 26, 1:00 pm – 2:30 pm**

Workshop: Challenges to Achieving Measurement Equivalence of Milk Protein Allergens in Food

**Monday, August 27, 12:00 pm – 5:00 pm**

Poster Presentations: Microbiological Methods, Botanical & Dietary Supplements, and Food Nutrition & Food Allergens

**Tuesday, August 28, 8:15 am – 9:45 am**

Roundtable: Breaking New Ground - Consumer Analytical Devices

**Tuesday, August 28, 10:15 am – 11:45 am**

Symposium: What Does Gluten Mean from the Analytical Perspective?

## Scientific Publications

### Improved Reference Materials for Gluten Analysis

#### Background

Products bearing a gluten-free label must not exceed the regulatory threshold of 20 mg gluten per kg of the product laid down in Codex Alimentarius Standard 118-1979. The most commonly applied analytical methods for gluten detection used to assess regulatory compliance are enzyme-linked immunosorbent assays (ELISA), but alternatives such as polymerase chain reaction (PCR) and liquid chromatography-mass spectrometry (LC-MS) are being developed. Gluten analysis poses several challenges, because gluten is a complex mixture of 100+ proteins with additional variations caused by genetic and environmental factors as well as food processing. Other points to consider are the selection of relevant target sequences, protein polymorphism, sample preparation and removal of interfering substances from the food matrix. Well-characterized reference materials (RM) are essential to help address these challenges, which is why an international consortium led by MoniQA Association has been working on identifying and characterizing wheat cultivars that are representative for the multitude of wheats grown worldwide and will shortly provide a new RM for gluten analysis.

#### Why a new standard material for gluten analysis?

Currently the most commonly used "gluten" standard is the Prolamin Working Group (PWG)-gliadin, which was prepared from a mixture of the 28 most commonly grown European wheat cultivars with the purpose of averaging variations originating from individual cultivars (van Eckert et al., 2006). Due to limited availability and applicability of the PWG standard and following the demand for more commutable materials, a new standard material has been extensively characterized and prepared from a mixture of five different wheat cultivars representing the major wheat cultivars globally and meeting stringent election criteria based on qualitative and quantitative protein fraction and peptide composition. The new material is provided as wheat flour and as ground incurred material in a cookie at concentrations of 10 and 30 ppm gluten, respectively. The materials are validated on the basis of the gluten and the total wheat protein content. The advantage of the RM is the validity and applicability with any analytical method (not only targeting the gliadin of wheat), including ELISA, PCR, LC-MS, and any emerging methods as well as a better representation of a food industry ingredient.



A direct comparison between results obtained with different methods will now be possible and a better standardization of the calibration material will reduce the uncertainty of results among different analytical approaches.

#### The way forward

The new MoniQA RM for gluten analysis will be commercially available from MoniQA Association and authorized distributors by the end of 2018. Final validation of the RM by an international ring trial is underway. The RM will be offered in a set containing a BLANK (ground gluten free cookie), a positive control (well characterized wheat flour, mixture of the 5 most representative cultivars worldwide), a LOW at 10 ppm gluten and a HIGH at 30 ppm gluten (incurred wheat flour in cookie).

**Roland Poms | MoniQA Association**

#### Reference

- (1) Hajas L, Scherf KA, Török K, Bugyi Z, Schall E, Poms RE, Koehler P, Tömösközi S. (2018). Variation in protein composition among wheat (*Triticum aestivum* L.) cultivars to identify cultivars suitable as reference material for wheat gluten analysis. *Food Chemistry* 267, 387-394. [\[Abstract\]](#)

## Upcoming Events

### 2<sup>nd</sup> International Conference on Food Analysis (2<sup>nd</sup> ICFA) & Workshop

Tracy Centre

November 20-22, 2018  
Melbourne, Australia

**Conference Topics:**

Food Allergens  
Food Fraud  
Food Safety & Food Trade in the Asia-Pacific Region  
Hemp Food  
PFOS  
Honey

For specific information please contact the organisers by email at [ICFA@measurement.gov.au](mailto:ICFA@measurement.gov.au)

### Food Safety Analysis 2018

Matrix Building Biopolis

November 27-28, 2018  
Singapore

**Conference Topics:**

Food Allergens  
Food Fraud and Authenticity  
Foodborne Contaminants  
Pesticides and agricultural contaminants  
and more



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### AOAC Food Allergen Community Newsletter

Contribute with articles, news items or suggestions.

Submission deadline for the 3<sup>rd</sup> issue of 2018: **Nov 23**

Send your articles to [AOAC.Allergens@gmail.com](mailto: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.

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