Editorial Comment

Oh Deer... Milk!

Forgive the pun, but it was hard to resist after the European Commission clarified what milk and egg are. For milk, it includes all farmed animals with mammary glands. So we may soon have to detect deer milk! But that is only one of the more interesting developments we have seen. The other is the tender of the UK Food Standards Agency (FSA), one of the bodies that tends to be frequently ahead of the game. It is for production of quality control materials for food allergens. The tender is running until early October. In Australia and New Zealand, lupin has been added to the list of food allergens requiring mandatory labelling. In the United States, US FDA has developed a Food Safety Plan Builder, which includes specifically food allergens. In addition, some other states have updated their requirements for restaurants and mass catering outlets to keep consumers safe. You also get a summary update from an allergen symposium and workshop that was held in May in Australia.

And, last but not least, it was Eisenhower who said: ‘Neither a wise man nor a brave man lies down on the tracks of history to wait for the train of the future to run over him.’ Bearing that in mind, we have seen several consumer analytical devices for food allergen and gluten testing that either have already made it to the market or will do so shortly. Various stakeholders identified the need for guidance for these devices and a working group was formed which is in the process of finalizing the first guidance document for consumer analytical devices.

Enjoy the read!

Bert Popping Editorial Board Member
Over the past years, with the reduced prices of sensors, the general trend towards miniaturization, increased speed of CPUs and bulk manufacturing capabilities, several devices have been manufactured, that allow consumers to analyze products for certain characteristics. An example that I frequently see in my LinkedIn feed is advertising for the Scio device, manufactured by the Israel-based company Consumer Physics.

This device is small, handheld and, using its NIR sensor, able to measure certain nutritional parameters and also identify certain drugs. It connects to your smartphone via Bluetooth and sends the raw data to the cloud where they are processed, analyzed and the result is returned to your smartphone, in case of drugs often even with the molecular formula.

For food allergen analysis, several devices also made it already to the market or are en route. And while potential inaccurate readings of nutritional values may not put your health immediately at risk, this is a different story for devices measuring substances causing adverse health effects.

If an allergic consumer makes a decision, exclusively based on the results by an allergen or gluten detecting device, and the result is erroneous, this can have severe consequences for the consumer as well as the food manufacturer.

Reasons for erroneous results are manifold, ranging from consumers not following manufacturers' instruction for the device, sampling non-representative portions or analyzing processed materials which may still contain allergens or gluten but where the target analyte is more difficult to extract, consequently giving rise to false negative results. On the other hand, false-positive results for allergen- or gluten-free products generated by consumer devices can put manufacturers brand reputation at risk and carry significant cost to prove absence of the target analyte.

While these are points of concern, there is also no question that, appropriately handled, consumer devices can be very useful tools to support the consumer's decision-making process. In addition, through cloud-based data analysis, it also bears the option of warning users and potentially food manufacturers, at an early knowledge stage of an allergen contamination of a particular product.

To ensure that minimum requirements for information to the user (consumer) are available, the devices are appropriately validated and provide useful sampling information, stakeholders from government, consumer and patients advocacy groups, food manufacturers and analytical tool providers (ELISA kit manufacturers and mass spectrometry manufacturer) formed a working group to produce guidelines for consumer analytical devices.

Since this group was established in March 2017 it worked in three subgroups (Consumer Instructions, led by Laura Allred; Sampling, led by Steve House and Validation, led by Bert Popping) which established the essential requirements for each of the aspects across the participating stakeholders.

The information from the three working groups has now been consolidated in a document that is currently shared for review among all stakeholders of the group. It is anticipated that this document will be published shortly.

Bert Popping in FOCUS GbR
EU Clarifies Allergen Labeling

In July, the European Commission published the Notice on the Provision of Information on Substances or Products Causing Allergies or Intolerances to assist consumers, businesses and authorities in understanding the new requirements of Regulation (EU) 1169/2011.

Probably, the most relevant clarification involves the definition of some of the food allergens requiring labeling. “Egg” must be used when the ingredient contains eggs from all farmed birds. Examples would include chicken, turkey, goose, duck, ostrich, quail. “Milk” is defined as milk from the mammary gland of farmed animals. Therefore, milk ingredients from, for example, cow, sheep, goat, water buffalo, llama, camel, mare, etc., should be included in the ingredient list. Milk from minor species, e.g. caribou, are rarely distributed in Europe, and they are consumed locally by some ethnic groups from other geographies, therefore, it is unlikely that they cause labeling issues.

What is the impact of the extended definition of milk and egg on detection methods? The obvious answer is that methods should be able to detect egg and milk from all farmed species, therefore an expanded cross-specificity panel should be included in validation studies of protein-based analytical platforms (e.g. ELISA, LFD, Mass Spectrometry).

The notice also adds additional clarifications to the labeling of products with or without ingredient lists and it indicates how to label several derivatives from the same allergen. In addition, it addresses exemptions and allergen information for non-prepacked foods.

Commission Notice

More Information

Carmen Diaz-Amigo FOCOS GbR

FSA Tender for QC Materials

The UK Food Standards Agency is well known for its leadership to safeguard food allergic consumers as well as for the openness in favor of dialog with food manufacturers and retailers in the UK.

The Agency’s latest initiative focuses on the field of analytical methods by opening a tender to develop Quality Control Materials for Food Allergen Analysis. The call indicates that the project needs to:

- define specific need for quality control/reference material
- commission research to address address those needs and
- develop suitable materials.

The following are important key dates:

- Call closing date: 9 October 2017
- Contract start date: 17 November 2017
- Contract end date: 31 March 2019

Carmen Diaz-Amigo FOCOS GbR
Lupin as Mandatory Allergen in Australia and New Zealand

Lupin belongs to the genus *Lupinus* and is part of the Leguminosae family. Traditionally lupin seeds were consumed in Mediterranean areas. More recently the consumption of lupin flour has vastly increased due to its nutritional value, especially in Australia, Europe and USA. Australia grows 75-80% of the total world lupin crop and therefore is the world’s largest producer. The usage of lupin flour in food products covers a wide range, e.g. pasta, bread, cakes, pizza, cream cheese, tofu sausages, spices, jam, noodles, ketchup.

The Australian and New Zealand Food Standards Code was changed recently (25th May 2017), making lupin a mandatory food allergen. Therefore lupin is to be declared when present in a food as an ingredient or component of ingredients, including food additives and processing aids in Australia and New Zealand (1). In support of the changes in the code, the Australian Food and Grocery Council and the Allergen Bureau issued supporting guidance documents for industry. Topic covered included time to comply with the new code, when lupin is a direct ingredient and there may be contact (2).

In Europe, lupin allergy is well documented and medical literature reported cases of severe allergic reactions, therefore the European Union (EU Regulation No. 1169/2011) has made lupin a mandatory allergen to be labelled on all containing food products (3).

Lupin allergy was first reported in Australia in 2004 by Smith et al. (4), showing severe allergic reactions to lupin, with no cross-reactivity to peanut or soy. In 2007, Campbell et al. (5) found matching correlation for lupin sensitized patient between skin prick testing (SPT), sensitization and allergic symptoms. No correlation for cross-reactivity to other legumes could be identified (5). In a Study by Goggin et al. (6), SPT of ten lupin allergic patient showed that three patient had positive SPT to peanut and soy. (6) Three more unpublished studied undertaken in Australia report lupin allergy, summarised by Food Standards Australia New Zealand (FSANZ) (7). The sensitization rate of peanut allergic patient to lupin was reported for children to be 25% and 41% for adults, respectively (7). A study by Foley et al. (8) demonstrated that sera from lupin allergic patients bind to different lupin proteins.

The nutritional properties and popularity of lupin will increase the available food products containing lupin (in Australia and globally). The different applications of lupin in food production often result in poor labelling visibility of lupin, when used as a food ingredient in food products, which is often referred to as hidden food allergens. The increased consumption of lupin containing food products will likely lead to more individuals experiencing allergic reactions to lupin.

The evidence of lupin allergy in Australia and the risk assessment undertaken by Food Standards Australia and New Zealand concluded that the clinical data from Australia on lupin allergy fulfils the international criteria for significant new allergens (7).

Martina Koeberl, Dean Clarke & James Roberts
The National Measurement Institute of Australia

References

(2) Australian Food and Grocery Council (AFGC) (2017) Lupin Information.
New Food Allergen Rules and Tools in the US

New rules and tools are targeting personnel and operators of establishments serving food directly to allergic consumers, e.g. restaurants, schools and other food facilities, since they play a key role in ensuring the safety of allergic consumers. Such efforts are aimed to ensure that measures are developed. The following are several government initiatives, state and federal, aimed to support food producers and catering business in the implementation of programs aimed to reduce risk of unexpected food allergen reactions.

Ensuring the safety of restaurant allergic customers

Illinois joins the US states of Maryland, Massachusetts, Michigan, Rode Island, and Virginia in the efforts to protect allergic consumers. An amendment to the Section 5 of the Food Handling Regulation Enforcement Act (410 ILC 625), modifies the Section 3.06 and adds Sections 3.07. The new addition to the rule requires food service establishments to have food service sanitation manager follow nationally recognized industry standards for allergen safety and allergen awareness. In addition, the rule also mandates that at least one manager should be present during operation hours. The purpose is to ensure that food served in restaurants is safe to allergic consumers by minimizing the risk of allergen cross-contact is minimized and well as to provide customers accurate allergen information. The new rule became effective on August 25th of 2017.

Control of Food Allergens in Schools

In addition to the assistance that schools receive from allergic consumer organizations, e.g. Food Allergy Research & Education (FARE), the U.S. Government has also developed initiatives to support these institutions. In 2013, the Center for Disease, Control and Prevention (CDC) published a Voluntary Guideline for Managing Food Allergies in Schools and Early Care and Education Programs. Later, in 2015, CDC released the Food Allergies in Schools Toolkit, which is composed of a number of documents and training material aimed to manage food allergies by the different staff roles (e.g. administrators, nutrition professionals, schools nurses, transportation staff).

Food Safety Plan Builder

As part of the programs to support food producers to comply with the Food Safety Modernization Act (FSMA), the US Food and Drug Administration has made available the Food Safety Plan Builder (FSPB), an optional tool to help develop specific food safety plans and to meet requirements of current Good Manufacturing Practices (cGMP), Hazard Analysis and Risk Preventive Controls for Human Food regulation. The FSPB is publicly available. In addition, the FDA has developed training videos and a user guide to assist the operator and understand the tool. Among other safety control topics, the FSPB includes a section specifically targeting Food Allergen Preventive Controls. For questions and additional information the FDA has made available a contact email: FoodSafetyPlanBuilder@fda.hhs.gov.
Summary of the 2nd Food Allergen Management Symposium 2017 & 2nd Asia Pacific Food Allergen Management Workshop (21-24 May 2017 Sydney, Australia)

The 2nd Food Allergen Management Symposium 2017 (FAMS2017) including the Second Asia Pacific Food Allergen Management Workshop was held 21-24 May 2017 at landmark Darling Harbour, Sydney. The conference venue, Australian National Maritime Museum, provided a perfect setting for bringing together some of the world’s leading food allergen experts – and over 160 delegates, from 102 organisations and 10 countries - as they sought to address the needs of the food allergic consumer.

The variety of speakers and range of topics presented over three full days successfully reflected the conference theme of “Global harmonisation of food allergy management – collaboration, innovation, science and communication”, and showed the willingness of all to be engaged for the delivery of better food allergen management outcomes. The Allergen Bureau of Australia and New Zealand was delighted to co-organise FAMS2017, along with the ARC Training Centre for Advanced Technologies in Food Manufacture of the University of New South Wales; National Measurement Institute; and University Laval.

FAMS2017 provided great opportunities to postgraduates to showcase their research. The poster and the 3-min presentations covered a wide range of hot topics in the field, ranging from new food allergen identification to precautionary allergen labelling surveys.

The Allergen Bureau were pleased to award the Allergen Bureau travel grant for postgraduate or early career researchers to Ms Ji Liang, ARC Training Centre for Advanced Technology in Food Manufacture, School of Chemical Engineering, University of New South Wales, for her poster on 'Development of a sensitive ELISA for detection of fish allergens from the southern hemisphere fish species'. Fish is one of the major food allergens that cause the IgE-mediated food allergy. Due to the cross-reactivity between fish species, strict avoidance of all fish species is recommended to fish allergic patients to prevent recurrence. The current commercial test kits for fish protein detection are largely developed for northern hemisphere fish. This study will fill the gap of sensitive immunoassay available for detection of southern hemisphere fish species.

Some key findings from FAMS2017 were that:

- The international view of the Reference Dose concept has shifted significantly in recent years. This was evidenced by the number of presentations which made positive mention of both, the Reference Dose concept, generally, and the VITAL Scientific Expert Panel Reference Doses (Taylor et. al. 2014; Allen et al 2014), specifically. Both local and international regulators, and clinicians (although not all), are moving towards acceptance and adoption of allergen Reference Doses;
- There are challenges for those working with the allergic consumer (clinicians, dieticians, consumer groups) in conveying the efforts of the food industry to their own stakeholders. Ongoing sharing of viewpoints and challenges between all stakeholders is the only way forward to delivering acceptable outcomes for all stakeholders;
- Food service, hospitals and catering are key stakeholders that still need to be fully engaged. In Australia, the National Allergen Strategy is working on this need, with significant contribution from the Allergen Bureau;
- Continuing the discussion is critical to achieving our common objective of protecting the allergic consumer in a practical and pragmatic way. Clear and consistent communication, at both a local and international level, is key.

We look forward to reviewing progress at FAMS2019.

Ray Murphy | Allergen Bureau
Upcoming Events

AOAC Food Allergen Community Meeting  
(131st AOAC Annual Meeting)
Tuesday, September 26, 2017  
4:45 pm - 6:45 pm  
Atlanta (GA), USA

Jupiter Yeung and Carmen Diaz-Amigo, co-chairs of the AOAC Food Allergen Community, would like to invite you to participate in the annual meeting. This has been a very active year full of different initiatives. As on previous occasions, we promise lively discussions with a significant amount of information exchange. The following is the meeting agenda, which includes an overview of the different meeting topics.

- Welcome and Introduction
- SMPR development for the quantitative detection of Egg and Milk by ELISA | Samuel Godefroy & Jupiter Yeung
- SMPR for Quantitation of Gluten in Oats | Joe Boison
- Guidance for Consumer Devices for gluten and allergen detection | Bert Popping
- Community Updates
- Short Oral Presentations:
  - The Use of Visual Examination for Determining the Presence of Gluten Containing Grains in Gluten-Free Whole Commodities | Laura Allred
  - Using LCMS with Appropriate Measurement Units for supporting Precautionary Allergen Labelling | Gavin O’Connor
- Additional business
- Adjourn.

Allergen Scientific Sessions at the AOAC Annual Meeting:

- Challenges in Food Allergen Management: Effective Tools and Practical Considerations. Co-chaired by Carmen Diaz-Amigo & Gavin O’Connor

AOAC Food Allergen Community Newsletter

Contribute with articles, news items or suggestions.
Submission deadline for the 3rd issue of 2017: Nov 17
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 AOAC.Allergens@gmail.com