AOAC Food Allergen Community

NEWSLETTER

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NEWSLETTER ARCHIVE

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Editorial Comment

The calendar of 2020 seems to have fewer months: January, February, March, Covid, December. And still, despite all the challenges we are facing with the pandemic, the food allergen community saw a number of new developments. For one, there is the concept of food safety culture, that also impacts how food allergens are deal with on the premises of food business operators (FBOs) – Richard Fielder reports about this. Then there are new proposed amendments to EC regulation 852/2004 to further minimize the risk of cross contamination. Cesare Varallo looks at the legal aspects and consequential challenges for FBOs. On the analytical side, AOAC has held two Thought Leaders meetings on food allergens and gluten to identify (analytical) gaps and needs, and suggest possible solutions for improvement. Neil Shepherd and Carmen Diaz-Amigo report updates from around the world, including the most recently held joint FAO/WHO ad hoc group meeting to assess if the current list of food allergens listed by Codex Alimentarius is still current.

Wishing you all a wonderful and safe festive season and a happy 2021!

Bert Popping Editorial Board

Featured Articles

A new dimension to food allergen analysis?
The potential influence of food safety culture on allergen analysis

Whilst this year has brought many significant changes, one of those producing a seismic shift for the food industry has been the concept of food safety culture - the organisational buy-in to attitudes, values, and beliefs. It has been almost universally adopted: in the revised Codex CXC 1-1969 standard, the GFSI 2020 requirements (IFS 7, BRCGS 8, SQS 9), the to be revised Regulation (EC) 852/2004 and in the FDA 'new era of smarter food safety' initiative. Consequently, it is reasonable to consider its potential impact on food allergen analysis. Thus, when faced with complex issues to resolve, such as with out of specification results (usually received as we are about to leave the office on a Friday afternoon), could our organisational culture determine our behaviour towards pursuing the right outcome?

Behavioural science

As analytical scientists, we are used to the practice of questioning assumptions, reasoning with logic and considering all possibilities. These processes of critical thinking also make for a robust food safety culture. Conversely, our willingness to accept false impressions (e.g. such as can occur with sampling) or perceive what we want to while ignoring opposing viewpoints (i.e. selective perception), do not.

The 'Friday afternoon' scenarios of out of specification results (for example) often leave us in two minds, that is to say our rational and emotional minds are in turmoil, with our rational mind trying to redefine or veto the inputs of our emotions (e.g. to shut down the PC and leave). Ordinarily, they work in tight harmony to guide us in our decisions, with our emotions informing the operations of our rational mind and vice versa.

Gluten in a milled cereal sample

Consider a gluten-free bakery, where the risk assessment typically places much of the measures to control gluten upon screening of raw materials entering the factory (e.g. oats). Whilst the onsite and laboratory gluten tests being used may have had some method validation conducted to demonstrate that the test performance is fit for purpose, the analytical variation originating from sampling are rarely adequately assessed. Too often large variation between the onsite and laboratory results (e.g. 'not detected' and >20 mg gluten/kg respectively) are observed. When faced with such scenarios, in conjunction with tight time constraints, we employ mental shortcuts (called an affect heuristic) to solve the complex problem quickly and efficiently, framed by the emotional state we are experiencing at the time. If our rational mind prevails, repeat analysis is performed and an improved grind in sample preparation and closer adherence to the test protocol for sample extraction, now leads to detection of gluten with the onsite test. Invariably, the issue is assessed to have been addressed at this stage and senior management press to move on. A subsequent well informed root cause analysis of the issue should establish that these are actually lower-level symptomatic causes, the underlying higher-level causes being the small test portion size and log-normal distribution of gluten in the oat raw material (Fritz et al., 2017). Research demonstrates that the skewed distribution of gluten in oats is more likely to lead to false negative results even with experienced operators following best practice. The corrective action should include taking a larger test portion size and performing replicates, though an organisational culture favouring quick resolutions may hinder reaching the same conclusion.

Cleaning validation & verification

Other applications of allergen testing may also have a propensity towards false results. For example, cleaning is one of the main interventions to prevent allergen cross-contact, especially when segregation within a factory is not possible. There can be inconsistent results in validation studies and routine verification testing due to many reasons, including from variations in the swabbing technique, that leads to a

conundrum when interpreting results. Our past experience may increase our tendency to interpret results based on our previously held beliefs (i.e. confirmation bias) providing us with a false impression. If root cause analysis is conducted that considers the latest research, the underlying higher-level causes should include recommending swabbing in triplicate per testing area in order to decrease the risk of false negatives (Barrere et al., 2020) - rather than the current practice of swabbing a test area without replication, which may also be insufficient to challenge our previously held beliefs.

Recommendation

When such issues discussed above are not adequately understood and addressed, the industry's confidence in allergen testing is undermined – which is a detriment to our community. Within AOAC, there is recognition of the general analytical challenges, especially with sampling: 'all our sophisticated efforts toward improving methods, validating methods and advancing analytical technology are swamped by a void in understanding the science related to selecting a representative test portion' (Thiex, 2019). Beyond recognising these important analytical challenges, we should also consider incorporating into our best practice guidance for industry some understanding of the behavioural science underlying organisational food safety culture; for example, by encouraging critical thinking processes. By doing so, it would help users of allergen test kits and analytical services to interpret results better and translate them into meaningful food safety decisions.

References

Fritz, R.D., Chen, Y. & Contreras, V. (2017). Gluten-containing grains skew gluten assessment in oats due to sample grind non-homogeneity. Food Chemistry 216, 170–175. https://doi.org/10.1016/j.foodchem.2016.08.031

Barrere, V., Theolier, J., Lacroix, S., Zbylut, S., Valdez, A., Collopy, N., Lahey, B. & Godefroy, S. (2020). Stability of milk and gliadin on swabs during 7 days under different storage conditions. Food Control 110, 107054. https://doi.org/10.1016/j.foodcont.2019.107054

Thiex, N. (2019). New Sampling Methods section. AOAC Inside Laboratory Management. Nov/Dec.

Richard Fielder | Bio-Check

EU – Regulation EU 852/2004 Amendments Related to Allergens' Cross Contamination Prevention

As we all know, in the European Union the allergens' cross contamination is not particularly regulated, both regarding advisory statements on the pack (c.d. "PAL" = Precautionary Allergen Labelling) and food hygiene practices.

Under a food safety perspective, the Regulation (EC) No 852/2004[1] provides very broad principles to prevent food related health risks – including some elements that might be of use for a correct allergen management – but is not mentioning even once the word "allergies", "allergens" or "cross contamination".

The Regulation (EU) No 1169/2011[2] on food information to consumers defines precisely the labelling rules applicable to allergens contained in the products, but is silent about "PAL". The only reference is in art. 36.3, lett. a)[3] , establishing that the Commission shall adopt implementing acts about the information on the possible and unintentional presence in food of substances or products causing allergies or intolerances. But the long-awaited acts never came.

This year, in the wave of the EU Green Deal the EU Commission tabled few amendments to Regulation (EC) No. 852/2004. The initiative aimed to:

- improve food safety in the EU, by bringing EU standards into line with new international standards about **cross contamination of allergens**[4] ;
- introduce "**food safety culture**" concept in EU regulatory framework:
- ensure appropriate food safety measures are taken when **food is donated for charitable causes and reduce food waste**;

and went under public consultation from 9th July to 6th August 2020.

Regarding allergens, both Annex I (related to hygiene rules for primary production) and Annex II (hygiene rules for other food business operators) of the Regulation (EC) No. 852/2004 will be modified as follows:

1) Annex I

In Part A, Section II, the following point 5a is inserted:

"5a. Equipment, conveyances and/or containers used for the harvesting, transport or storage of one of the substances or products causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the harvesting, transport or storage of any food not containing that substance or product, ***unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product****."*

2) Annex II:

In Chapter IX, the following point 9 is inserted:

"9 Equipment, conveyances and/or containers used for the processing, handling, transport or storage of one of the substances or products causing allergies *or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the processing, handling, transport or storage of any food, not containing that substance or product,* ***unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product****."*

In substance the proposal aims to limit or reduce the promiscuity of conveyances, containers and machineries, but in both cases the amendments will allow such use if there is a visible absence of food debris.

It is pretty clear – as emerged also by different opinions expressed during the public consultation – that if from one side the obligation to avoid any promiscuity of the equipment would create a very difficult situation for the industry (especially for primary production), on the other side the visual check option seems a far too easy way out from a real allergen management, exposing allergic consumers to usual risks.

The amendments have not yet been implemented due to COVID-19 crisis and might still be subject to changes. The situation shall be monitored in 2021.

Cesare Varallo foodlawlatest.com

1 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

2 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004

3 *"3. The Commission shall adopt implementing acts on the application of the requirements referred to in paragraph 2 of this Article to the following voluntary food information:*
(a) information on the possible and unintentional presence in food of substances or products causing allergies or intolerances;"

4 In particular the recent CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS - CXC 80-2020, adopted in 2020 by the Codex Alimentarius.

News

AOAC International's Food Allergen and Gluten Thought Leaders Meetings

Allergens and gluten are – across many jurisdictions – one of the top-five reasons for food product recalls. While AOAC has already established Standard Method Performance Requirements for Food Allergens and Gluten as well as a stakeholder guidance document some years ago, there are still unmet needs and gaps. Closing these will allow the food industry to control processes better to avoid undeclared allergens in their products. Besides, on the analytical side, it would allow food testing technology providers to calibrate assays more consistently, ultimately allowing laboratories to produce more consistent results.

To identify the gaps and also discuss approaches to close them, AOAC hosted two Thought Leader panels in December, one on food allergens and the second on gluten.

The panels were introduced by Palmer Orlandi, Deputy Executive Directors and Chief Science Officer at AOAC. The panels were led by Samuel Godefroy of Université Laval (Quebec, Canada) and Bert Popping of FOCOS – Food Consulting Strategically (Alzenau, Germany).

The Food Allergens Thought Leaders Panel took place on December 2 and comprised presentations by Jennifer Gerdts of Food Allergy Canada, highlighting the challenges of food allergic consumers and new challenges arising from a shift towards plant-based proteins. Melanie Downs from FARRP provided the food industry perspective and highlighted challenges, especially with processed foods. Carmen Diaz-Amigo presented the achievements of the AOAC Allergen Community. Palmer Orlandi and Samuel Godefroy summarized the ideas discussed to close the analytical gaps towards the end of the session.

The Gluten Though Leaders Panel took place two weeks after the food allergen panel, on December 16. Tunde Koltei from the board of the Association of European Coeliac Societies AOECS gave a very good overview of the challenges of their members, living with celiac disease. Tunde highlighted aspects for the gluten-free certification program, which was later discussed as some of the gluten-free schemes in North America have noticeable differences in their requirements. Bert Popping then highlighted the previous work of the AOAC experts on gluten, including a community guidance document for the validation of ELISA assays for food allergens and gluten, a work led by Terry Koerner of Health Canada, and the Gluten SMPR published in 2017. Subsequent to that the need for reference material for calibration and quality assurance of gluten assays was discussed. Not all topics could be discussed due to the shortness of time, and it was decided that follow-up discussions will need to take place.

Both thought leader meetings were attended by high-level food industry executives, showing the importance of this topic not only for food testing technology providers and food testing laboratories but also for the food industry.

Bert Popping in FOCOS

Update on Allergens from Australia

This year has been a challenge for the world and all eyes are now on 2021. The following is a summary of current topics in Australia covering conferences, VITAL and news from government and industry.

VITAL 3.0. Vital Scientific Expert Panel (VSEP) recommendations 2019

The VSEP reviewed the data from clinical (low-dose oral) food challenges from both published and unpublished studies. The papers were sourced from Australia, the United States and the European Union and over 3,400 clinical data points were collated. The data included in the review was required to meet defined quality criteria to ensure that resulting allergen thresholds were statistically sound. The data set was analysed by applying a new Stacked Model Averaging program (Wheeler et al, 2019) for each allergenic food. The Stacked Model Averaging program produces a single curve for each allergen from which Eliciting Doses may be derived. The VSEP identified the ED01 (which is the dose of the total allergen protein that is predicted to produce objective symptoms in 1% of the allergic population) which were adopted as the Reference Doses for VITAL 3.0.

http://allergenbureau.net/vital/vital-science/
http://allergenbureau.net/vital-scientific-expert-panel-2019-summary-recommendations-the-new-allergen-reference-doses-for-vital-program-version-3-0/

The following papers discuss the process for how the Reference Doses within VITAL 3.0 were developed:

- Wheeler MW et al. (2020), Bayesian Stacked Parametric Survival with Frailty Components and Interval-Censored Failure Times: An Application to Food Allergy Risk. Risk Analysis. https://doi.org/10.1111/risa.13585
- Westerhout J et al (2019) Deriving individual threshold doses from clinical food challenge data for population risk assessment of food allergens. J Allergy Clin Immunol. 144 (5):1290-1309. https://doi.org/10.1016/j.jaci.2019.07.046
- Remington et al (2020) Updated population minimal eliciting dose distributions for use in risk assessment of 14 priority food allergens. Food Chem Toxicol. 2020 Mar 13;139:111259. https://doi.org/10.1016/j.fct.2020.111259

Allergens Bureau

The New Guide to VITAL allergen labelling is available in the following link:
http://allergenbureau.net/wp-content/uploads/2019/10/Food-Industry-Guide-to-the-Voluntary-Incidental-Trace-Allergen-Labelling-VITAL-Program-Version-3.0_Web.pdf

The VITAL Standard is a supplementary certification program for food manufacturers that are already certified to GFSI recognised food safety management standards that include allergen management. The VITAL Standard is certified by Certification Bodies accredited to ISO/IEC 17065:2012 (or subsequent version) and audited by auditors trained in the VITAL Standard and registered with The Allergen Bureau Ltd. Manufacturers that achieve VITAL certification may use the VITAL Mark on the products within their scope of certification.
http://allergenbureau.net/vital/vital-standard/

Government and Industry

The Australian Food and Grocery Council has published a *Food Industry Guide to Allergen Management and Labelling*
https://www.afgc.org.au/wp-content/uploads/2019/10/FINAL-Food_Industry_Guide_to_Allergen_Management_and_Labelling_ANZ_2019_VD3.pdf

FSANZ is reviewing the Food Safety Code to clarify the requirements on how the declaration of regulated food allergens (P1044 – Plain English Allergen Labelling): https://www.foodstandards.gov.au/code/proposals/Pages/P1044PlainEnglishAllergenLabelling.aspx

The Australian House of Representatives Standing Committee on Health, Aged Care and Sport, following the Parliament Inquiry, has prepared the report *Walking the allergy tightrope - Addressing the rise of allergies and anaphylaxis in Australia*:
http://allergenbureau.net/parliamentary-inquiry-makes-recommendations-for-allergen-labelling-training/
and https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Allergiesandanaphylaxis/Report

A multi-jurisdictional and stakeholder meeting has been organised to investigate the cause and impact of peanut in cashew. The findings still need to be formalised.

A new initiative from the Allergen Bureau in collaboration with the National Measurements Institute has formed the Allergen Testing Special Interest Group with the purpose to provide advice on the analysis of food allergens in Australia: http://allergenbureau.net/wp-content/uploads/2020/02/ATSIG-Pesto-Briefing-Note_v1.0_07Feb2020.pdf

NATA has published Supplementary Accreditation Criteria (SAC) for testing of allergen proteins and Gluten:
https://www.nata.com.au/accreditation-information/accreditation-criteria-and-guidance/nata-accreditation-criteria-nac-packages/laboratory-accreditation-iso-iec-17025/category/24-food-and-beverage

Concerns re substitution of ingredients due to lack of supply – but no further action around that at this point

Skills Impact is undertaking a review of food and beverage training packages and have revised units to improve the areas of allergen management. This aligns with some of the recommendations from the Parliament Inquiry referenced above.
https://www.skillsimpact.com.au/food-beverage-and-pharmaceutical/training-package-projects/food-beverage-processing-project/

Thank you to Robin Sherlock (Safefood QLD) and Jasmin Lacis Lee (BV) for contributing information to this update.

Best wishes for the holiday season and 2021!

Neil Shepherd | NATA, Australia

News in Brief

Europe

The European Commission has published the 2019 Rapid Alerts for Food And Feed Report. Food allergens accounted for about 30% of the notifications, and milk, gluten and soya were the most reported cause. More Information

The Food Standard Agency (UK) has published a Technical Guidance for business on the new requirements for allergen labeling for prepacked for direct sale. The requirements will apply from Oct 1, 2021. More Information

North America

The US Food and Drug Administration has issued the Final Rule on Gluten-Free labeling of Fermented and Hydrolized Foods. The key element for compliance is to show that the ingredient or food is gluten-free before fermentation or hydrolisis. More Information

The US Food and Drug Administration has also issued a draft Guidance for Industry on the Voluntary Disclosure of Sesame as an Allergen. This will address the labeling of sesame when used as a flavoring agent or a spice ingredient. Moreover it will help consumers identify the allergen in products where sesame is not obvious ingredient, e.g. tahini. Comments to the draft are possible until Nov 1, 2021. More Information

The Canadian Food Inspection Agency has published the report of findings of targeted surveys for undeclared allergens and gluten in spices and herbs. The surveys were conducted in the periods April 1, 2015 to March, 31, 2016 and April 1, 2017 to March 31, 2018. About 34% of the 598 samples tested in the first period and 23% out of 359 samples analyzed in the second period were positive for at least one allergen (including beta-lactoglobulin, egg, hazelnut, almond peanut, sesame, soy, and gluten). More Information

South America

The Chilean Congress unanimously approved and sent to the Senate the bill that modifies the Regulation 20.606 on nutritional composition of food and its advertising, to incorporate celiac disease and gluten. More Information (in Spanish)

Codex Alimentarius

Codex Alimentarius has adopted the Code of Practice on Food Allergen Management for Food Businesses Operators (CXC 80-2020). The document addresses allergen control activities along the food chain from primary production to retail and food services. More Information

An additional initiative of Codex on food allergens has to do with the revision of the General Standard for the Labeling of Prepackaged Foods (GSLPF). It aims to review the general provisions on allergen labeling. A second activity will focus on the development of a guidance on the use of precautionary labeling. The revision on the GSLPF has already started in an *ad-hoc* join FAO/WHO meeting, which has taken place virtually (Nov 30 - Dec 11). The meeting gathered a multidisciplinary group of expert tasked with the revision and validation of the Codex priority list of allergens through risk assessment. More Information

Carmen Diaz-Amigo FOCOS

Upcoming Events

4th Food Allergen Management Symposium

May, 2021
(date to be confirmed)

Australia and New Zealand
(locations to be confirmed)

Blended event (virtual + in person)

For more information, visit:
http://allergenbureau.net/the-4th-food-allergen-management-symposium-fams2021-may-2021/

AOAC Food Allergen Community

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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