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Editorial Comment

Never a dull day!

Many of us in the food allergen community have been in the business for a decade (or two). What I found is that rarely a month goes by where nothing happens in relation to food allergens.

Reflecting on the major events of the past, we can highlight the FDA recalls for food allergens exceeding those of microbiological origin, the mahaleb that resulted in positives for almond in several ELISA assays, and the numerous failed attempts of industry organisations and governmental bodies to move EFSA to recommend threshold or action levels for food allergens. The response of EFSA was the same as always: insufficient data. In this context, it is interesting that, between 2011 and 2019, the VITAL experts managed to find as many as 562 individual challenge studies, in addition to the already existing 206. With that, they were able to determine reference doses for additional allergens and adjust the doses of other food allergens already listed in VITAL 2.0. All are now based on ED₀₁. This issue contains two articles addressing the all-new VITAL 3.0. Robin Sherlock reports about the latest updates from the Allergen Bureau and Richard Fielder puts these new values in perspective for the food industry.

And if that is not enough excitement already, Melanie Downs reports about the challenges of the new requirement to label sesame as food a allergen, which is exclusive in the state of Illinois and not required in any of the other US states. Reiko Adachi explains the dynamic of Japanese food allergen labelling requirements, based on clinical surveys, and the increase of prevalence of some food allergens in the latest survey.

And last but not least, we want to ensure that also in the forthcoming AOAC annual meeting in Florida, we hear the updates and news in the field of food allergens. So do not forget to submit your session proposals before December 31, 2019!

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Featured Article

Impacts of Illinois Sesame Bill on U.S. Food Allergen Labeling

In the United States, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) sets forth regulations for the declaration of major allergens on labels of packaged foods regulated by the U.S. Food and Drug Administration (FDA). According to FALCPA, manufacturers must indicate the intentional addition of eight major food allergens and ingredients derived from those foods, namely: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. The list of major allergens identified in FALCPA is similar to priority allergen lists in other parts of the world, although a number of jurisdictions have included additional foods such as sesame, molluscan shellfish, lupin, celery, and mustard.

On July 26, 2019, the governor of the state of Illinois signed a bill ([HB2123](#)) into law ([Public Act 101-0129](#)), which impacts the labeling of sesame in the state. The bill amends the Illinois Food, Drug and Cosmetic Act such that a food is misbranded:

“(s) If it contains sesame, is offered for sale in package form but not for immediate consumption, and the label does not include sesame.”

Given the brevity of the amendment, manufacturers may be left with a number of questions about compliance with this regulation.

Is the Illinois labeling regulation preempted by FALCPA?

The answer to this question remains somewhat unclear. While FALCPA is explicitly preemptive (21 U.S.C. 343-1(a)(2)), the Illinois regulation does not specifically state that sesame is required to be labeled because it is a major allergen. Information from the bill’s sponsor indicates that sesame allergy concerns were part of the consideration for introducing the bill, but there is no explicit mention of food allergens in the text itself. Whether the Illinois regulation would be considered to be in conflict with FALCPA may be up for debate.

Should sesame be labeled as an allergen on products in Illinois?

This question also may not have a definite answer as the Illinois regulation does not provide details on how sesame must be labeled. Under FALCPA, major food allergens can be declared either in the ingredient statement or in a Contains statement that directly follows the list of ingredients. However, the Contains statement can only include major food allergens, and FDA-regulated products have been recalled previously when foods not considered to be major allergens were listed in the Contains statement. It is unknown whether the FDA would exercise similar authority for inclusion of sesame in a Contains statement.

Will the FDA add sesame to the list of major allergens?

On October 30, 2018, the FDA issued a [request for information](#) on sesame as an allergen in foods. Since then, there have been more than 4,800 comments [submitted to the agency](#). At this point it remains unclear how the FDA may proceed on this issue, as there are no required actions following the request for information.

What are likely impacts of the Illinois law?

Sesame allergy continues to be an issue of concern for stakeholders in the U.S. While much of the discussion around sesame has focused on labeling, the potential additional requirements to manage and control sesame as a major allergen would also have substantial impacts on food manufacturers. Given that many food products are sourced, produced, and distributed across multiple state lines, a decision in one state can have broad but potentially variable effects across the industry. Arguably, all stakeholders want to prevent reactions in sesame-allergic individuals, but differing state and federal regulations may only serve to add confusion for manufacturers and allergic consumers alike.

Melanie Downs | University of Nebraska, FARRP

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News

Update on Allergens from Australia

2019 has been a productive year for the food allergen community in Australia. A number of allergen community initiatives have recently been launched and more are scheduled for later this year.

The Allergen Bureau (AB)

The Allergen Bureau (AB) has launched free risk review interactive webpage which provides a step by step view of the risk review process and allows the user to examine each part of the production line. The tool allows users to deep dive into specific areas of production to inform a whole of process risk review. This webpage is free to all and is the culmination of a collaborative project with contribution from individuals and companies with a comprehensive knowledge of allergen risk review and management and years of hands on experience.

<http://allergenbureau.net/risk-review>

An analysis webpage has been added to the Allergen Bureau website. This webpage sets out basic principles of allergen analysis including the options available and best practise for their application. The webpage will be updated regularly and the information available will continue to be expanded.

<http://allergenbureau.net/food-allergens/food-allergen-analysis/>

Allergen Bureau has also announced that a summary of the 2019 VITAL Scientific Expert Panel Recommendations is available. This summary includes recommendations for new Allergen Reference doses for VITAL® Program Version 3.0. The VITAL Scientific Expert Panel (VSEP) met in late 2018 and early 2019 to develop new recommended Reference Doses for the Allergen Bureau VITAL® (Voluntary Incidental Trace Allergen Labelling) Program. The VSEP noted a significant increase in the number of suitable data points from individuals who had undergone challenge studies for most allergens. Sufficient data were available for egg, hazelnut, lupin, milk, mustard, peanut, sesame, shrimp, soy, wheat, cashew, celery, fish and walnut and as a result ED01 doses were identified for all allergens. For further information please see:

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

Further initiatives will follow the release of VITAL 3 in October 2019 which will include the release of updated Training information and tools.

Food Standards Australia New Zealand (FSANZ)

FSANZ continues to collect data on food recalls and to interrogate the data to provide industry with information regarding the causes of allergen recalls.

<http://www.foodstandards.gov.au/industry/foodrecalls/recallstats/Pages/default.aspx>

FSANZ has a proposal to review allergen labelling: FSANZ – Plain English Allergen Labelling (PEAL) which will consider clarification of the terminology of fish, seafood and molluscs and the separation of wheat, molluscs and individual tree nuts. The intention is to consider consistent terminology and location the information required

<http://www.foodstandards.gov.au/code/proposals/Pages/P1044PlainEnglishAllergenLabelling.aspx>

Australian Food and Grocery Council (AFGC)

In October 2019 the Australian Food and Grocery Council (AFGC) in conjunction with the Allergen Bureau are launching a revised Food Industry Guide to Allergen Management and Labelling (FIGMAL) with a planned release date of Q4 2019.

<https://www.afgc.org.au/industry-resources/food-labelling-and-allergen-guide>

Regulators

The State of Victoria (Aust) has implemented a system of notifications of anaphylaxis resulting in hospitalisation, with a rapid investigation, if these are associated with food consumption. The data from this system has provided insight into triggers for anaphylaxis and will continue to be collated and reviewed. Further information on this system is available here:

<https://www2.health.vic.gov.au/public-health/anaphylaxis-notifications>

A presentation given at the Food Allergens Management Symposium 2019 in Melbourne by the Victorian Department of Health is available on the Allergen Bureau Website.

http://allergenbureau.net/wp-content/uploads/2019/05/CLIFFORD_2019-Presentation-Anaphylaxis-Notification-System-FAMS2019.pdf

The National Allergy Strategy (NAS) has been rolled out a series of tools including training modules on allergen management for the food service industry.

<https://nationalallergystrategy.org.au/>

In response to the increasing incidence and impact of food allergy in Australia, the House of Representatives Standing Committee on Health, Aged Care and Sport has commenced an enquiry into allergies and anaphylaxis in Australia. The Committee will consider a number of issues including causes, allergy management, impact and support services. A public consultation period closes in November 2019. For more information or to post a submission, go to the Parliament Australia website:

https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Allergiesandanaphylaxis

Laboratory Accreditation

The National Association of Testing Authorities, Australia is publishing criteria for the accreditation of testing for allergen proteins and Gluten in Q4 2019.

<http://nata.com.au>

This is actually only a snapshot of the work taking place so for further information please contact:

- Allergen Bureau <http://allergenbureau.net/>
- Rob Sherlock: robsherlock7361@gmail.com or
- Neil Shepherd: Neil.Shepherd@nata.com.au



134th Annual Meeting • September 11-17, 2020 • Orlando, Florida

CALL FOR PROPOSALS

The AOAC Technical Programming Council (TPC) invites all AOAC Members and other interested individuals to submit proposals for the scientific sessions offered at the 134th AOAC Annual Meeting and Exposition. Proposals may be submitted to chelf@aoac.org between OCTOBER 1 and DECEMBER 12, 2019.

SUBMISSION CRITERIA

- Relevance to current AOAC programmatic areas
- Originality of topic and speakers
- Appropriate breadth and depth for a 90-minute session
- Educational content
- Scientific novelty

AOAC will send out acceptance/rejection letters no later than December 31, 2019. Once a proposal is accepted, all participants must pre-register for the Annual Meeting. Because there is only a limited budget for travel funding, most participants are responsible for their travel and lodging expenses.

SUBMIT A SCIENTIFIC SESSION PROPOSAL

All scientific sessions will be 90 minutes in length. All proposals will be reviewed by the TPC. Proposals should include:

- Area to which you are submitting
- Scientific session title
- Brief abstract of the scientific session
- Individuals participating in the session
- Contact information

SUBMIT AN INDIVIDUAL PAPER PROPOSAL

All individual proposals will be reviewed by the TPC, and if accepted, grouped with other accepted proposals to form a 90-minute scientific session. Proposals should include:

- Relevance to current AOAC programmatic areas
- Originality of topic and speakers
- Appropriate breadth and depth for a 90-minute session
- Educational content
- Scientific novelty

For more information, visit www.aoac.org/news/2020-annual-meeting-call-for-proposals

Food Allergy Labeling in Japan: Recent Trends in Tree Nuts and Gluten

Food allergy labeling in Japan started in 2002. Currently, the labeling of egg, milk, wheat, buckwheat, peanut, shrimp/prawn, and crab, which are referred to as “specific allergenic ingredients,” is mandatory by Cabinet Office Ordinance. Moreover, at present, the Consumer Affairs Agency notification recommends the labeling of another 21 ingredients (subspecific allergenic ingredients), including almond (described below).

Since the start of food allergy labeling, a nationwide survey of food allergies has been conducted every 3 years. This survey collects 1-year data of food allergy cases from allergists who cooperate with the survey, and information obtained from this survey has been reflected in mandatory or recommended labeling lists as necessary. For example, sesame seed and cashew nut were added to the recommended labeling list in 2013 on the basis of the survey results. The latest survey results in 2018 showed an increase in the number of patients allergic to some tree nuts such as walnut and almond (Table 1).

Table 1. Changes in the ratios of walnut and almond allergy cases (1)

Ingredient		Survey year		
		2012	2015	2018
Walnut	Walnut / Total* (%)	1.4	1.5	5.2
	Ranking	9	8	4
Almond	Almond/ Total (%)	-	0.3	0.4
	Ranking	-	20	16

*Total number of cases in one survey is approximate

Therefore, Consumer Affairs Agency issued a notice on September 19, 2019, to add almond to the recommended labeling list. Additionally, the upgrading of walnut from a subspecific to specific allergenic ingredient is also under consideration.

Gluten-free food is crucial for patients with celiac disease and wheat allergies. The Codex standard for labeling “gluten-free food” is less than 20 ppm gluten. Rice is the main grain consumed as staple food in Japan, and rice flour has also been used in various foods. Originally, rice does not contain gluten; therefore, recently, rice flour is often used as a substitute for wheat flour. Japanese rice flour industry organization formulated voluntary guidelines for gluten-free

labeling of rice flour products in 2017 with the support of the Japanese Ministry of Agriculture, Forestry and Fisheries. In these guidelines, the gluten labeling standard is set at 1 ppm or less, referred to as “nongluten,” because they wanted to differentiate rice flour from other gluten-free foods and make it more useful for patients with celiac disease and wheat allergies and those who prefer gluten-free foods not only in Japan but also worldwide.

As a method to confirm the accuracy of the nongluten labeling of rice flour products, we verified the ability of wheat ELISA kits to measure gluten in rice flour by interlaboratory validation with 10 laboratories. Rice flour containing wheat protein extract equivalent to 1, 2, 3, or 5 ppm gluten was used as sample. Gluten was quantified in each sample using three types of wheat ELISA kits [FASTKIT ELISA Ver. III (NH Foods Ltd.), Morinaga FASPEK ELISA II (Morinaga Institute of Biological Science, Inc.), and Allergeneye ELISA II (Prima Meat Packers Ltd.)], which are used as official screening methods for wheat protein in processed foods in Japan. The results were satisfactory: recovery rates were 90%–100%, repeatabilities (RSDr) were 3.9%–5.8%, and reproducibilities (RSDR) were 14.4–18.0 with 1 ppm gluten (2). Based on these results, the above guidelines stipulate that these ELISA kits should be used to verify the nongluten labeling of rice flour products.

It has been 17 years since the food allergy labeling system started in Japan, and several revisions have been made as necessary. I would like to keep this community informed of any changes in the Japanese labeling system.

Reiko Adachi

National Institute of Health Sciences, Japan

(1) Research report on food labeling related to food allergies, the Consumer Affairs Agency, Government of Japan (2012, 2015, and 2018).

[https://www.caa.go.jp/policies/policy/food_labeling/food_sanitation/allergy/\(in Japanese only\)](https://www.caa.go.jp/policies/policy/food_labeling/food_sanitation/allergy/(in_Japanese_only))

(2) Adachi R et al. (2017) Jpn J Food Chem Safety 24, 88-93 (in Japanese only)

Thresholds

How high? Determines How Low?

How high are the allergen consumption thresholds for populations of allergic patients? And how little needs to be detected in a serving size? These are separate ends of the allergen threshold debate that must now be re-assessed, as on the 28th October 2019, the new Reference Doses for **VITAL 3.0** were released.

New Reference Doses: When Reference Doses (RD) are converted for varying serving sizes to support allergen management, the challenge for analysis is to detect such low levels in the larger serving sizes. This newsletter has already discussed (Volume 9, Issue 1) these analytical challenges with the Dutch scientific committee's proposed Reference Doses, which are significantly lower than both the Belgian and German (based on VITAL 2.0) proposals (Table 1).

The revised Reference Doses for VITAL 3.0 are now all based on the ED01; the Eliciting Dose at which 1% of the allergic population would react with objective symptoms to the total allergenic protein. Some of the Reference Doses have increased compared to VITAL 2.0 (egg, milk, shrimp – Figure 1) whilst others have reduced (wheat, lupin, sesame, soya – Figure 2). Of those that have increased, the detection of milk protein in serving sizes of 500g (e.g. a ready meal) still prove problematic for currently available ELISAs, except when using the available casein assays. For those Reference Doses that have reduced, the Lower Limits of Quantitation (LLOQ) of available ELISAs also make the detection of mustard and sesame beyond current ELISA capabilities for meal-size servings. For the first time, there are Reference Doses for celery, fish (finfish), cashew (& pistachio) and walnut (& pecan). The detection of these “tree nuts” in meal-size servings (e.g. 500g) is difficult by ELISA. For celery, it means that in the absence of readily available ELISAs, PCR is the method of choice, with the limitation of detecting celery DNA rather than protein.

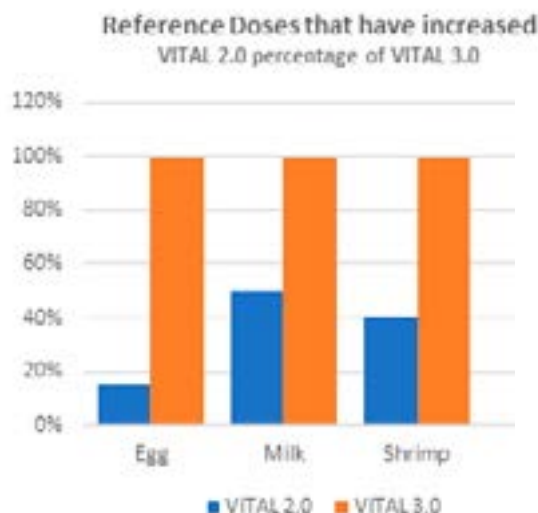


Figure 1. VITAL 3.0 Reference Doses that have increased.

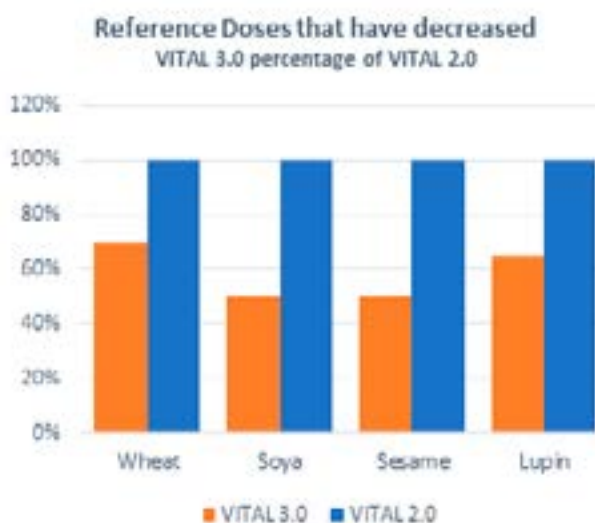


Figure 2. VITAL 3.0 Reference Doses that have decreased

Table 1. Proposed Action Limits for peanut, milk & egg in Europe compared with VITAL 3.0

Allergen	Belgium		Germany		The Netherlands		VITAL 3.0	
	RD (mg protein)	100g serving (mg/kg)	RD (mg protein)	100g serving (mg/kg)	RD (mg protein)	100g serving (mg/kg)	RD (mg protein)	100g serving (mg/kg)
Peanut	1.1	11	0.2	2	0.015	0.15	0.2	2
Milk	1.2	12	0.1	1	0.016	0.16	0.2	2
Egg	0.3	3	0.03	0.3	0.0043	0.043	0.2	2

Recommendations for analysis: In allergen management, analysis can help to support decisions on: How safe? How clean? and How to label? For analysis to provide objective evidence for these purposes, it is becoming increasingly important to consider (amongst other things): (i) reporting results in mg protein/kg of food or at least providing the conversion factor to do so, in order to help interpret results in-line with protein Reference Doses and Action Limits (ii) providing information about the composition of standards used in ELISAs; Reference Doses relate largely to the whole, unprocessed food (iii) assessing the analytical range of the assay to be used, to ensure that it is appropriate for the serving size (iv) be aware that reporting results near to the assay's Limits Of Quantitation, where assay precision is less optimal, can be problematic and (v) utilising well-designed processes of sample selection and preparation, to ensure that the analytical Test Portion is both homogeneous and representative.

Table 2. Action Limits for peanut, milk & egg proteins and ELISA Limits of Quantitation (LLOQ)

Allergen	Action Limits - mg protein/kg with Serving Size				ELISA LLOQ
	5g	50g	100g	500g	mg protein/kg
Peanut	40	4	2	0.4	0.25
Milk	40	4	2	0.4	0.5
Egg	40	4	2	0.4	0.4

The outcomes of the ThRAII project (funded by EFSA until 28-Feb-2021) are expected to further inform this discussion.

Richard Fielder | Bio-Check

Upcoming Events

11th Food Allergens Methodologies Workshop

May 4-6, 2020

JW Marriott Edmonton Ice District
Edmonton, Canada

For additional information visit:

farrp.unl.edu/food-allergens-methodologies-workshop



Keerati / freedigitalphotos.net

AOAC Food Allergen Community Newsletter

Contribute with articles, news items or suggestions.

Submission deadline for the 1st issue of 2020: **Feb 28**

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