

# Allergen Bureau

## The Threshold Challenge

Debbie Hawkes

Allergen Bureau Director /

NZIFST Conference 2023

3–5 July, Dunedin

**HawkinsWatts**

Informing the  
food industry



# Allergen Bureau

- Membership based organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods
- Established in 2005, pre-competitive, 'not-for-profit', Allergen Bureau directors provide voluntary, unpaid services

Become a member

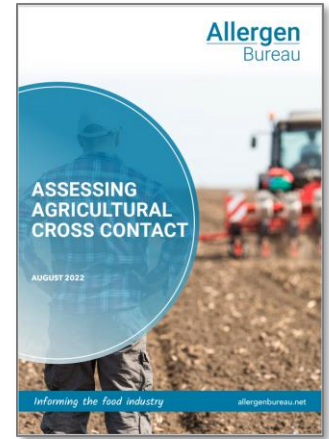
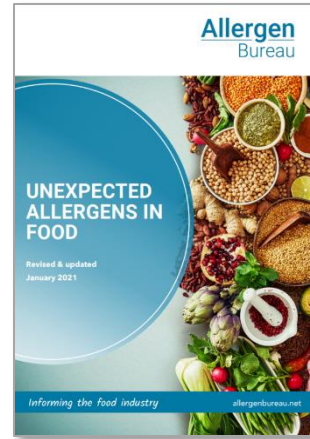
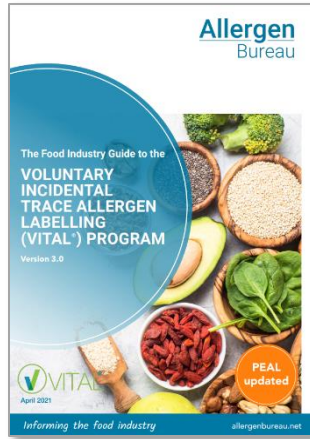
Global Member



Full Members



- ALDI Stores
- BBF Hull Limited
- SoFine Foods



**Allergen**  
Bureau

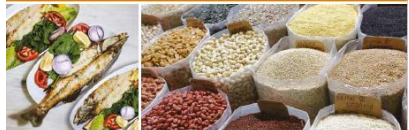
<https://allergenbureau.net>

Resources  
for the  
Food Industry

# FAO/WHO Ad Hoc Expert Consultation on Risk Assessment of Food Allergens

Food and Agriculture Organization of the United Nations | World Health Organization | 14 FOOD SAFETY QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS  
PART 1: REVIEW AND VALIDATION OF CODEX ALIMENTARIUS PRIORITY ALLERGEN LIST THROUGH RISK ASSESSMENT

Food and Agriculture Organization of the United Nations | World Health Organization | 15 FOOD SAFETY QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS  
PART 2: REVIEW AND ESTABLISH THRESHOLD LEVELS IN FOODS FOR THE PRIORITY ALLERGENS

Food and Agriculture Organization of the United Nations | World Health Organization | 16 FOOD SAFETY QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS  
PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

Food and Agriculture Organization of the United Nations | World Health Organization

Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens  
Part 4: Review and establish exemptions for the food allergens  
FAO HQ, Rome, Italy: 14 - 18 November 2022  
SUMMARY AND CONCLUSIONS  
Issued in January 2023

RISK ASSESSMENT OF FOOD ALLERGENS  
PART 4: REVIEW AND ESTABLISH EXEMPTION FOR THE FOOD ALLERGENS





# Priority Allergen Recommendations

- Cereals containing gluten  
(i.e., wheat, rye, barley species and strains)
- Fish & Crustacea
- Eggs
- Milk
- Peanuts
- Sesame
- Specific tree nuts  
(almond, cashew, hazelnut, pecan, pistachio, walnut)



# Non-Priority Allergens

## Possible regional significance

- buckwheat
- celery
- lupin
- mustard
- oats
- soybean
- tree nuts  
(Brazil nut, macadamia, pine nuts)

## Emerging watch-list

- pulses
- insects
- kiwi fruit

# Threshold levels for priority allergens

Safety objective\*:

*“to minimise, to a point where further refinement does not meaningfully reduce health impact, the probability of any clinically relevant objective allergic response, as defined by dose distribution modelling of minimum eliciting doses (MEDs) and supported by data regarding severity of symptoms in the likely range of envisioned Reference Doses (RfD)”*

\*Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens  
- Final Report Meeting 2

**Allergen**  
Bureau





# Threshold levels for priority allergens

**Reference doses (RfD)** determined by dose-distribution modelling of results from DBPC challenge studies.

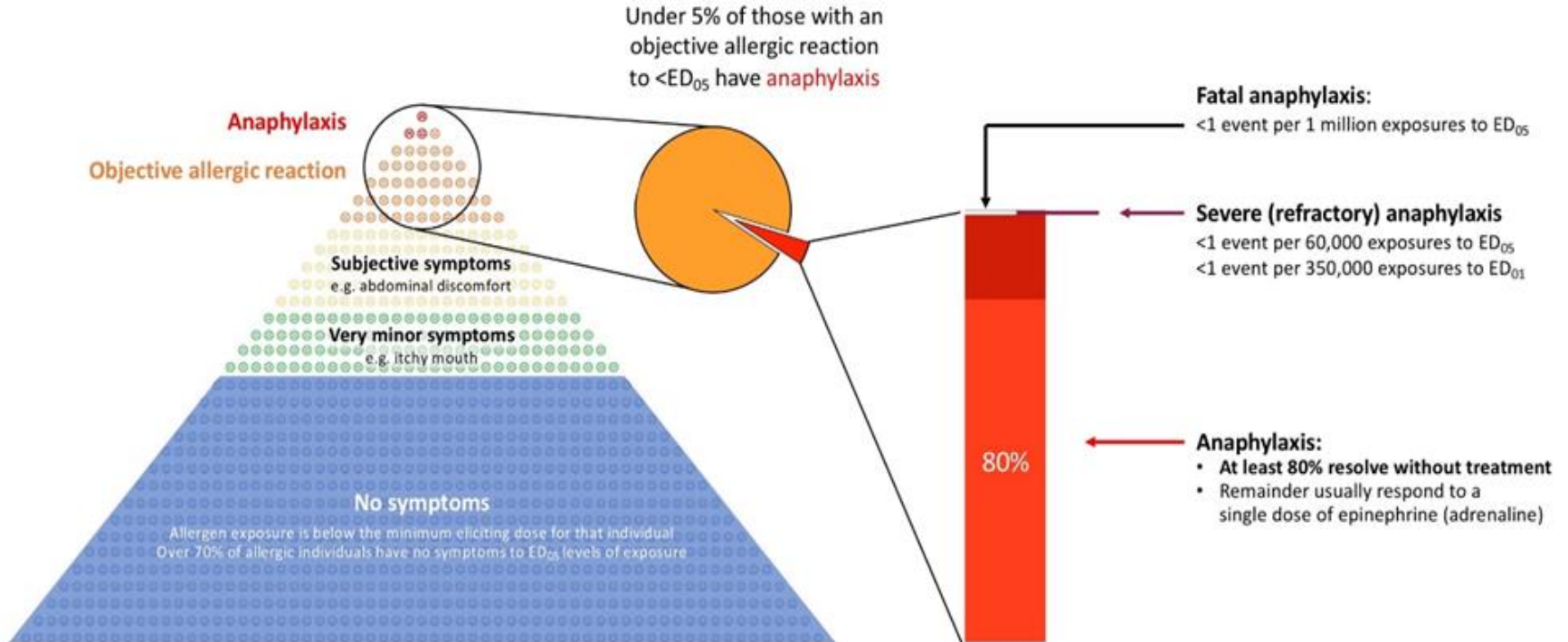
**Clinical data** indicated up to 5% of reactions at both ED01 and ED05 could be classed as anaphylaxis, although **none were severe**, based on the WAO definition.

**Fatal food anaphylaxis is very rare**  
(1 per 100,000 person-years in allergic population)  
& no fatal reactions are documented following exposure to doses at or below ED01 nor ED05.





# Hierarchy of risks faced by people susceptible to IgE-mediated food allergy, proportionate to their estimated occurrence for peanut in peanut-allergic individuals. *Turner et al, 2021*



# FAO/WHO Panel Reference Dose

	RfD Recommendation (ED05 based, mg total protein)	VITAL™ 3.0 RfD (ED01 based, mg total protein)
Walnut (& Pecan), Cashew (& Pistachio), Almond	1.0	0.03 0.05 0.1
Egg, Milk, Peanut, Sesame	2.0	0.2 0.1
Hazelnut	3.0	0.1
Wheat, Fish	5.0	0.7 1.3
Shrimp	200	25

# Stakeholder feedback to ED05 transition

*Food Manufacturers:*  
“But we’ve only just completed major label changes for PEAL”

*Allergy Consumer groups:*  
“Implement ED05 ASAP, to reduce PAL”

*Food Manufacturers:*  
“But PAL can be due to sporadic &/or particulates”

*Allergen Bureau: same message*  
“Eliminate, Reduce & apply QRA to use PAL”

A hand is shown holding a wooden block with the letter 'R' above a stack of three wooden blocks with letters 'I', 'S', and 'K' from top to bottom. The background is a light blue gradient.

## Stakeholder feedback to ED05 transition

- Reactions may increase, even if mild & transient
  - Consumer view to a higher incidence rate?
  - Enforcement agencies -  
Will there be a consistent approach?
  - Will my business perceive this as a higher risk, and be reluctant to change?
- If ED05 means a PAL is no longer required, what is the change management process?



## Next steps towards ED05

- Survey on PAL impact, opened 1-Jul
- Businesses asked for de-identified labelling outcomes, identifying only product category and complete a short survey
- VITAL online user or using QRA?  
Please contact [info@allergenbureau.net](mailto:info@allergenbureau.net)

**What is the  
impact expected in  
labelling outcomes,  
with a transition  
to ED05 in a  
program like VITAL?**



**WE NEED  
YOUR HELP!**

# More steps towards ED05

- International stakeholder engagement
  - Food Drink Europe
  - Food & Drink Federation (UK)
  - Food Standards Authority (UK) FSA
  - Other judications and industry stakeholder
- Coeliac patient advocacy groups
- Joint consensus statement on PAL to be developed

**Allergen**  
Bureau

## Food Allergen Management Consensus Statement

**IT IS THE RESPONSIBILITY OF CONSUMERS TO:**

1. declare their allergies and read food labels (including ingredient lists and allergen declaration statements), and
2. ultimately make their own judgement about the foods they choose to consume.

**WE CONSIDER THAT IN ORDER TO ENABLE CONSUMERS TO MAKE INFORMED DECISIONS ABOUT THEIR SAFETY:**

**IT IS THE RESPONSIBILITY OF PACKAGED FOOD MANUFACTURERS TO:**





1. follow robust allergen management practices including quantitative risk assessment, and
2. use clear, consistent labeling to inform consumers about that food's allergen content, including the possible presence of unintended allergens.




**IT IS THE RESPONSIBILITY OF FOOD SERVICE ESTABLISHMENTS/PROVIDERS TO:**

1. follow robust allergen management practices, and
2. ensure that staff understand and can inform consumers about the allergen content of the food they provide, including the possible presence of unintended allergens.

We recognise that the safety of consumers with food allergy is a shared responsibility of consumers, packaged food manufacturers, food service establishments/providers, health professionals, retailers, and regulatory and enforcement agencies.

This consensus statement is specific to consumers, packaged food manufacturers and food service establishments/providers, and is part of a strategy to improve the safety and quality of life of consumers with food allergy.

**How many should you / will you eat?**



# Standardised Reference Amount Project

- Collaborative project with AB and TNO
- Food Category Consumption data rather than company nominated Reference Amounts
- Another level of consistency and robustness – alignment with FAO/WHO recommendations
- Commercialisation of Food Intake Guide (EU, US), with the intent to incorporate AUS data
- Accessibility for VITAL and non-VITAL users
- Industry feedback/input as project progresses to measure impact





# THANK YOU

---

Don't forget to tell your ideas about this presentation and share it with us!

CONTACT US:



[info@allergenbureau.net](mailto:info@allergenbureau.net)

[allergenbureau.net](http://allergenbureau.net)

[@allergenbureau](#)