




# The latest updates on allergens – recalls, analysis, what's next

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2022 | September



A stack of four dark chocolate pieces is the central focus, resting on a dark, textured surface. The chocolate pieces are broken and layered, showing a rough, crystalline texture. Scattered around the base of the stack are numerous chocolate shavings and small pieces, creating a sense of a recently broken or broken-up bar. The background is a soft, out-of-focus brown, suggesting more chocolate or a similar material. The lighting is dramatic, highlighting the textures of the chocolate.

What has  
happened since  
FIAQ 2021?

# Federal funding for allergen prevention 2022

- Direct result of the Parliamentary Inquiry
- Secures \$26.9 million for research into prevention and management of allergy
- Establishment of National Allergy Council (NAC) & National Allergy Centre of Excellence (NACE)

## Australia leading the world: Federal funding secured for allergy prevention and management

30 March 2022

Allergy experts have applauded the \$26.9 million investment into allergy prevention and management announced in the Federal Government's 2022 pre-election budget.

The funding will lead to the creation of two vital organisations, the National Allergy Council and National Allergy Centre of Excellence (NACE), that will work together to deliver world-leading initiatives and research to improve consumer safety and prevent anaphylaxis deaths.

"Australia has been termed the 'allergy capital of the world' with more than 5 million Australians living with allergic disease. Allergy diagnoses and hospital admissions for life-threatening allergic reactions continue to rise," Maria Said, Co-Chair of the National Allergy Strategy and CEO of Allergy & Anaphylaxis Australia said.





# World First Consensus Paper:

- Completed in December 2020
- Collaboration between clinicians, consumers and industry
- Peer reviewed paper published April 2022, The Journal of Allergy and Clinical Immunology

<https://allergenbureau.net/wp-content/uploads/2022/04/Food-Allergen-Management-Consensus-Statement-final.pdf>

<https://doi.org/10.1016/j.jaip.2022.03.018>



A Bureau Veritas AsureQuality Joint Venture

## 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.

The bottom of the slide features a row of logos for the organizations involved in the consensus statement. From left to right, they are: Centre for Food & Allergy Research (a stylized 'G' logo), national allergy strategy (a colorful horizontal bar), Allergen Bureau (a logo with a triangle and a circle), ASCIA (Allergists and Anaphylaxists Society of Australia, with a logo of a person and a triangle), Allergy New Zealand (a logo with a flower and the text 'www.allergy.org.nz'), and FAMS (Food Allergy Management Society, with a logo of a person and a triangle).



# International legislation highlights

## USA

- Introduction of sesame 2021, 1<sup>st</sup> Jan 2023 compliance date

## UK

- Introduction of Natasha's Law 1<sup>st</sup> October 2021
- Applicable to prepacked food for direct sale
- Name of the food, ingredients list and allergens
- FSA consultation on PAL statements, report issued 2022

## JAPAN

- Added walnut

## INDIA

- Mandatory allergen labelling in effect 1<sup>st</sup> Jan 2022

# Allergen Bureau – New Resource

NOW AVAILABLE  
*Assessing Agricultural Cross Contact*

- Includes:
  - All things agricultural
  - Raw material questionnaire = risk rating
  - Risk rating informs sample numbers
  - Guidance on how to use the analytical data to inform allergen management and QRA



Download  
the new  
guide

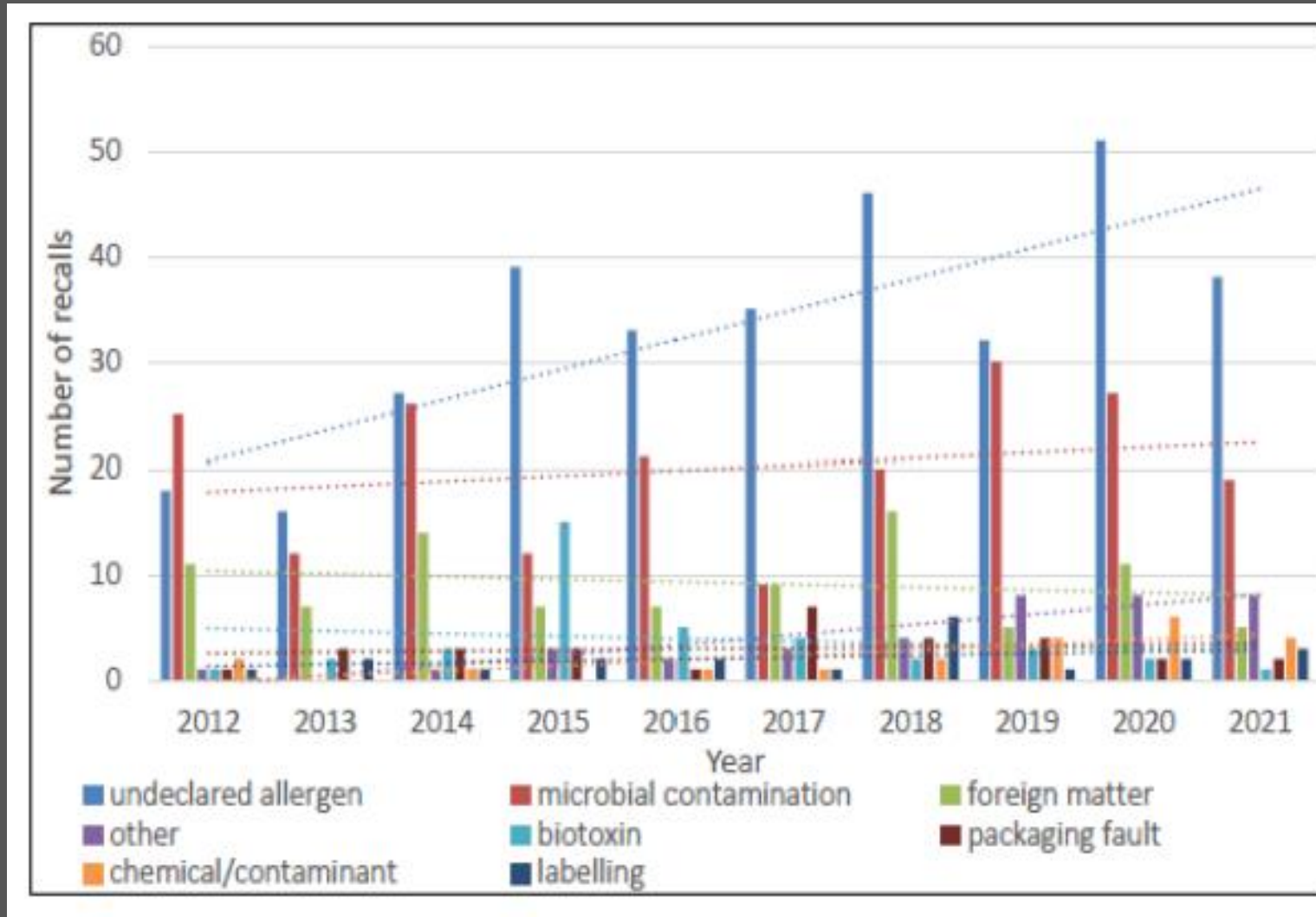
ALLERGEN BUREAU NEWS - AUG 22, 2022

<http://allergenbureau.net/resources/>



# Australian Recall Data

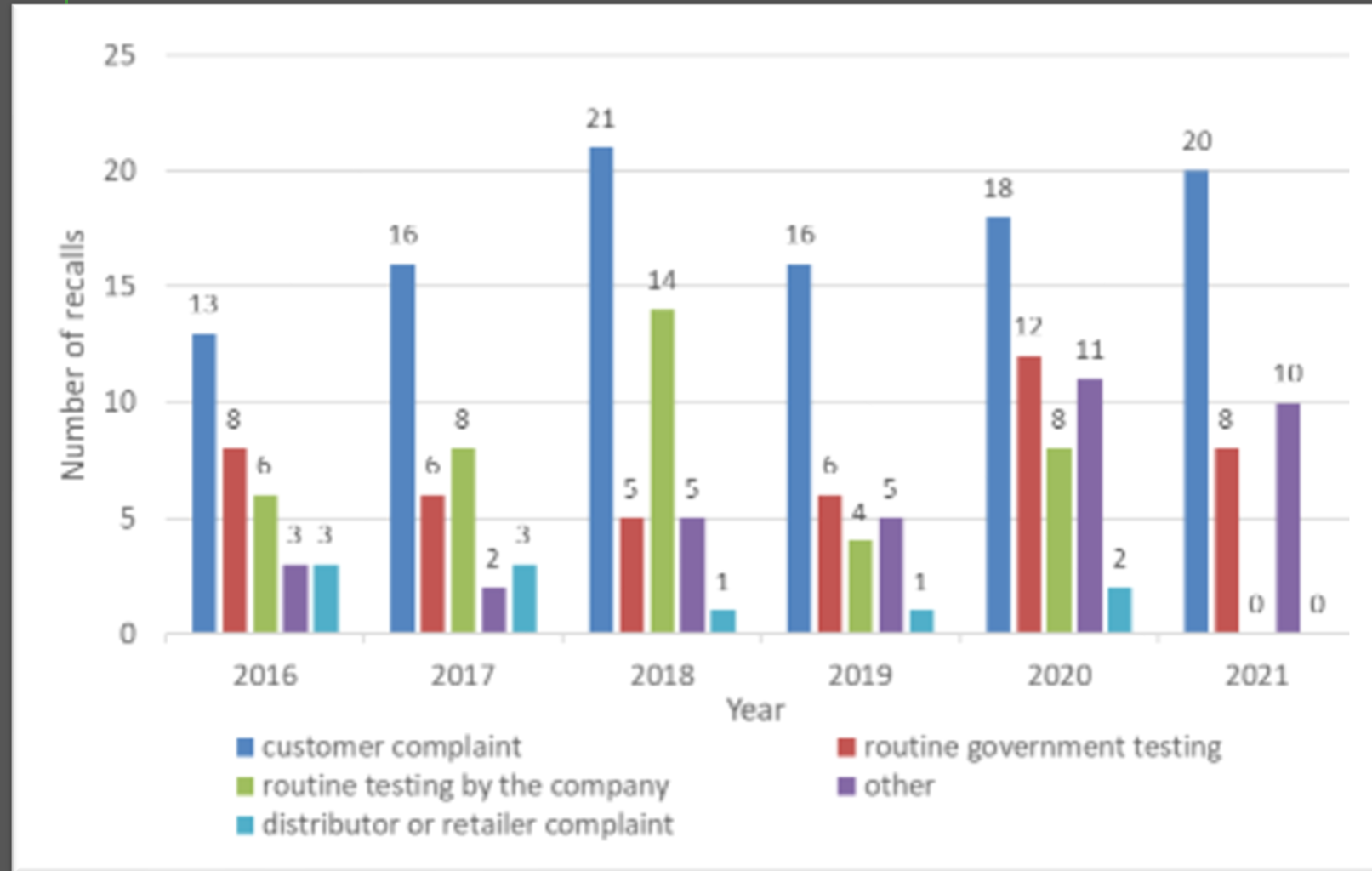
- Between 2011 – 2021
  - 335 recalls (43%) due to undeclared allergens
- Top 3 reasons (2016-2021)
  - Packaging errors
  - Supplier verification issues
  - Accidental cross contact



# What Initiated the Recalls?

2016-2021

- Leading reason for recalls
  - customer complaints

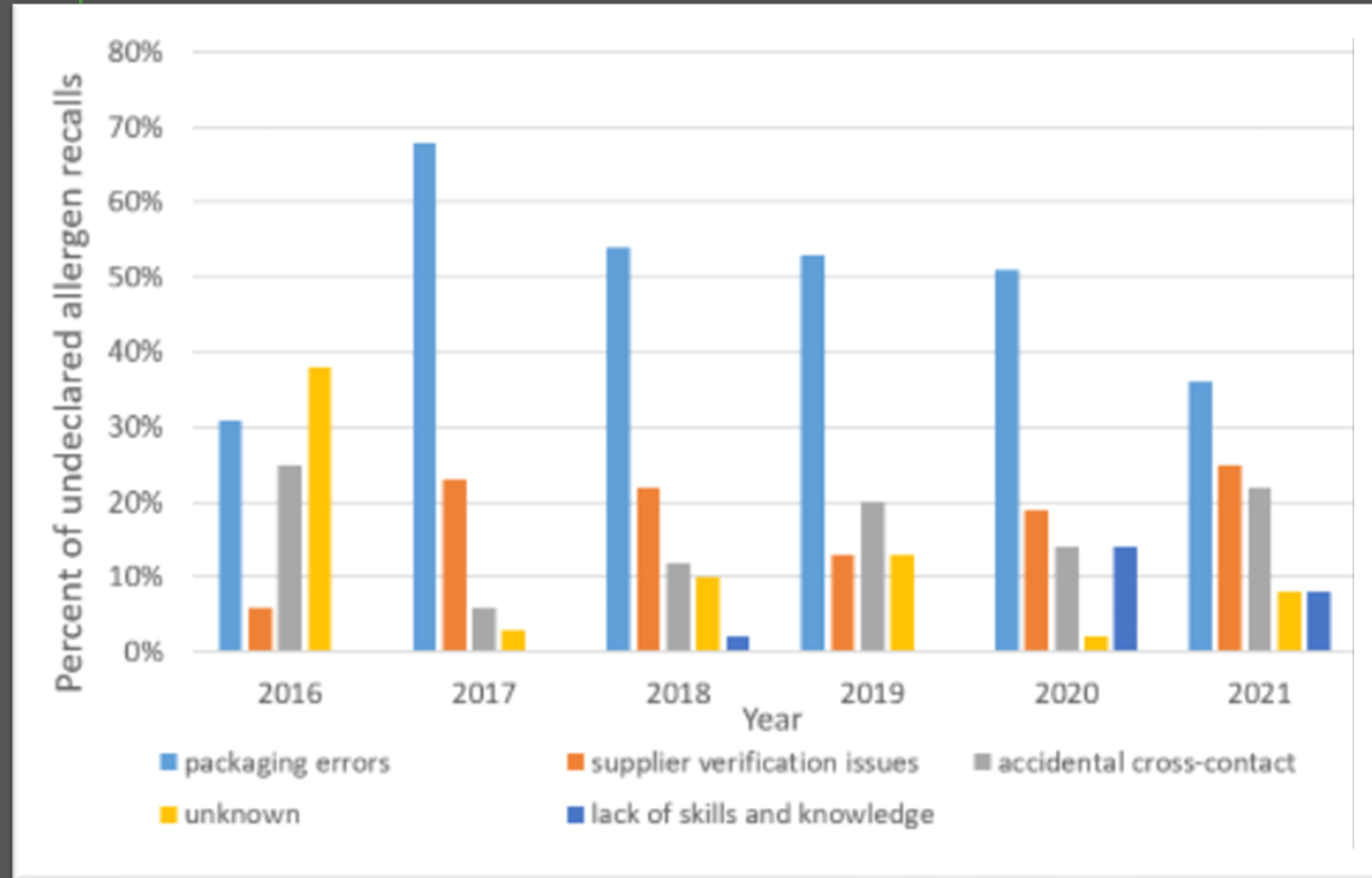




# Recall root cause

2016-2021

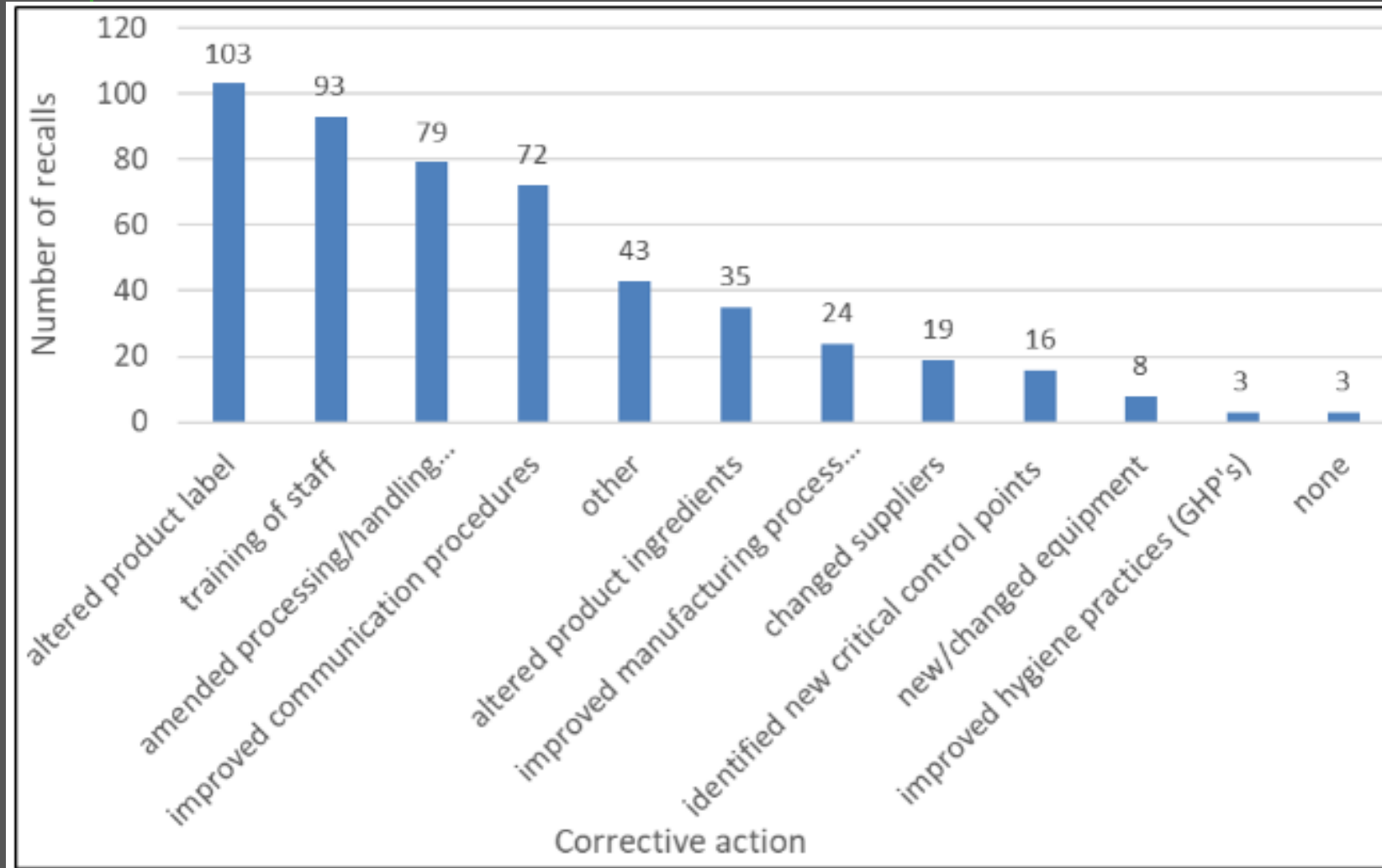
- Packaging errors are the leading cause
  - Incorrect label



# Root Cause Corrective Action

2016-2021

- Altered product label
  - Accidental cross contact
  - Supplier verification issues
  - Cause unknown
- Training
  - Packaging errors

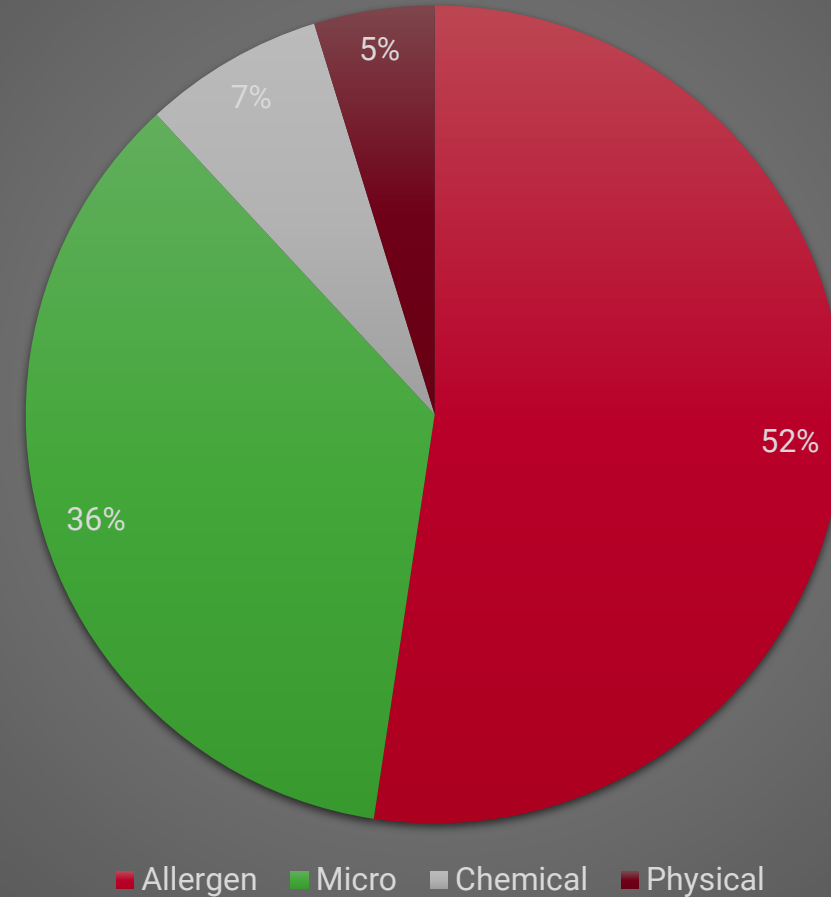




# Where are we in 2022?

- 22 undeclared allergens
  - 10 imported products
  - 8 products with claims
  - 9 due to milk

Recalls (as at 6/09/2022)



# Case Study 1: Peanut in Soy Lecithin



- Alert in Europe – April, June, July 2022
- Peanut present in varying levels (10 – 220ppm)
- Origin: India
- Cause: soy mill facility use for peanut?
- Global impact in the supply chain
- Significant impact in Australian not seen
- Recalls – none
- Regulatory & enforcement advice:
  - Conduct a risk assessment and update labelling if required



## Case Study 2: Soy in Xanthan Gum

- Soy present in varying levels
  - Discrepancies in results
- Origin: China
- Cause: Used in the fermentation process,  
? Processing failure
- Localised impact
- Recalls - ?
- May have driven labelling updates
- The Great Debate - ingredient /  
processing aid



A hand is shown holding a single puzzle piece in the foreground. The puzzle piece is a warm, golden-brown color. In the background, several other puzzle pieces are visible, some overlapping, creating a sense of depth. The background is softly blurred, focusing attention on the hand and the piece it holds. A green rectangular overlay is positioned on the right side of the image, containing the title text.

# An update on Allergen Analysis



# General Limitations

- No international standards (i.e. ISO)
- Not all kits have undergone AOAC independent assessment
- Current AOAC validation guidance does not cover all allergens and is generalised
- Standard reference materials only recently released (and not for all allergens)
- No standard reporting requirements



7 ppm Casein?

For the BVAQ kit =  
2.4 ppm milk protein  
(kits reports NFDM)

7ppm  $\beta$ -Lactoglobulin?

For the BVAQ kit =  
70 ppm milk protein  
(kits reports BL)

7 ppm of what???

- What is the kit measuring?
- What is the kit reporting?

7ppm Total Milk?

For the BVAQ kit =  
2.5 ppm milk protein  
(kits reports NFDM)



# Analytical change is coming!

## AOAC Gluten and Food Allergen Working Group (2021 – current)

- Reviewing validation requirements for kit manufacturers
- Current ELISA and LFD focus
- Standardised reporting units
  - Total Protein mg/kg (ppm)
- End user guidance document is likely on the completion





# What's on the horizon?



# THE FUTURE: *FAO / WHO Expert Consultation on Risk Assessment of Food Allergens*

## To inform Codex Committee on Food Labelling

1. Proposed changes to global priority allergens
  - Remove soy, lupin, mustard, celery, oats, molluscs, brazil nut, macadamia, pine nuts and sulphites
  - Consider region specific allergens
  - Pulses, insects and other foods (kiwi) added to "watch list"

<http://www.fao.org/3/cb4653en/cb4653en.pdf>



# THE FUTURE: FAO / WHO Expert Consultation on Risk Assessment of Food Allergens



## 2. Review and establish threshold levels in foods of the priority allergens

- Recommended Reference Doses at an ED05

	RfD Recommendation (mg total protein from the allergenic source)
Walnut (and Pecan*)	1.0
Cashew (and Pistachio*)	1.0
Almond**	1.0
Peanut	2.0
Egg	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Shrimp	200
Milk	[decision pending based on further data analysis]
Sesame	[decision pending based on further data analysis]

\* see considerations in full report  
\*\* provisional

	RfD Recommendation (mg total protein from the allergenic source)
Milk	2.0
Sesame	2.0

- Standardisation of analytical results to report "mg total protein of the allergenic food / kg food"

<https://www.fao.org/3/cb6388en/cb6388en.pdf>  
<https://www.fao.org/3/cb9312en/cb9312en.pdf>

# THE FUTURE: *FAO / WHO Expert Consultation on Risk Assessment of Food Allergens*

3. Review and evaluate the evidence in support of precautionary labelling
  - PAL is recommended to part of a regulatory framework
  - PAL should be based on Reference Doses, and only used when the RD is exceeded
  - On pack indication that a QRA has been performed, irrespective if a PAL statement is required
  - Compliance to Codex COP and other control programs is a prerequisite
  - Language should be simple, clear, unambiguous and not false and misleading
  - "Not suitable for" - yet to be determined
  - Consumer education is needed

[https://cdn.who.int/media/docs/default-source/food-safety/jemra/3rd-allergen-summary-report-13dec2021.pdf?sfvrsn=5415608\\_7](https://cdn.who.int/media/docs/default-source/food-safety/jemra/3rd-allergen-summary-report-13dec2021.pdf?sfvrsn=5415608_7)



# In summary – it's not all bad

- Australia continues to lead
  - Quantitative Risk Assessment - VITAL (est. 2007)
  - Thresholds (2011)
  - FSANZ Recall trending - no other jurisdiction does this globally (2016)
  - Clear, unambiguous allergen labelling (BP to PEAL)
  - Anaphylaxis Reporting in ED
  - NATA (ISO 17025) additional accreditation requirements for 3<sup>rd</sup> party labs performing allergen analysis
  - ATSIG (Allergen Testing Special Interest Group)
- Using the Australian Recall data
  - Get back to basics!
- Be proactive - the tools are there
  - Good Allergen Management & Quantitative Risk Assessment



The image shows the interior of a bus, viewed from the back of the cabin looking forward. The seats are red with yellow handrails. Blue vertical poles and horizontal bars are visible throughout the cabin. The lighting is dim, and the overall atmosphere is quiet and empty.

**Get on the bus, the rest of the world is catching up!**

# SAVE THE DATES

- All things allergens for 2.5 days
- Combines clinicians, researchers, consumer advocates, regulators, legislators and food industry
- First time in QLD
- International conference!
- Access to international experts
- Collaboration between Allergen Bureau, UNSW & NMI

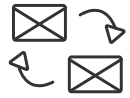


FOOD ALLERGEN MANAGEMENT SYMPOSIUM

30 MAY - 1 JUNE 2023



# THANK YOU



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