

# Allergen Bureau

## Allergen Bureau resources to assist in your risk assessments

### Presented By:

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President & Food Safety Manager -  
BVAQ

Integrity Compliance Solutions Webinar: BEST PRACTICES for your next Food  
Safety, Food Fraud & Supplier Assessments  
23<sup>rd</sup> February 2023



Informing the  
food industry



The Allergen Bureau is participating in this forum to promote best practice allergen management and risk assessment. Our involvement in no way infers that the service provider is preferred by the Allergen Bureau. The Allergen Bureau has many passionate and professional members who provide services to support industry. We are grateful to all who support the vision of a trusted food supply for allergenic consumers around the world. A full list of service providers can be found in our services directory

[Allergen Bureau Services Directory - Allergen Bureau](#)

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# Allergen Bureau

- The Allergen Bureau is the peak industry body representing best practice food industry allergen management globally
- 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

Global Member




Full Members



•ALDI Stores  
•BBF Hull Limited

# Resources Available

**Allergen Bureau**



**UNEXPECTED ALLERGENS IN FOOD**

Revised & updated  
August 2022

*Informing the food industry* allergenbureau.net

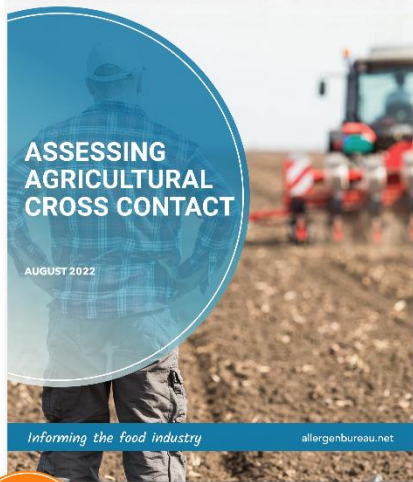
**Free Resources for Industry**

Unexpected Allergens in Food provides the food industry with a list of foods, ingredients and raw materials that may unexpectedly contain allergens.

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



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**ASSESSING AGRICULTURAL CROSS CONTACT**

AUGUST 2022

*Informing the food industry* allergenbureau.net

**Free Resources for Industry**

The guide assists industry to identify and manage agricultural cross contact risk.

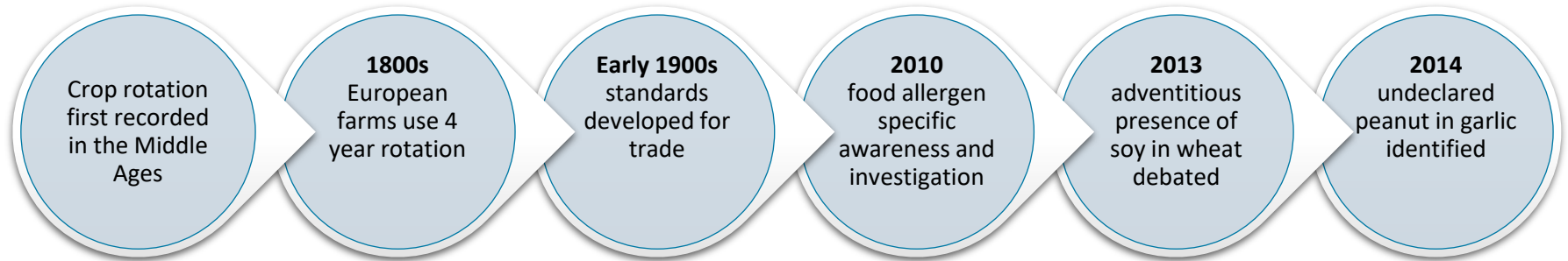
Download at [allergenbureau.net](http://allergenbureau.net)




**RAW MATERIAL RISK MATRIX QUESTIONNAIRE**

Risk Assessment Questions	Low Risk	Response Options		High Risk	Year Introduced	Total Score (0-25)	Quantity Observed	Number of Occurrences			
		Yes	No					0	10	25	
Q1. Is the material produced from an equivalent regulatory jurisdiction?	Yes	1	No	3							
Q2. Does the supply chain include growers or processors from international sources?	No	2	Yes (International)	5							
Q3. Is the supplier GFS certified?	Yes	2	No	3							
Q4. Does the supplier have a documented and robust allergen management plan?	Yes	2	No	3							
Q5. Does your contract have a robust understanding and resolution of the applicable supply chain's CoA structure, provided unless covered due to a shared risk management strategy (contract, identity and testing etc.)	Yes	2	No	3							
Q6. Are other allergenic crops used in crop rotation or grown in close proximity?	No	2	Yes	3							
Q7. How is the commodity stored / contained?	Compartments	2	Intermixtures	3							
Q8. Are effective measures in place to prevent or minimize potential allergen cross contact from shared equipment and facilities throughout the supply chain?	Yes	2	Partially	3	No (Continuous)						
Q9. Are there storage and separation measures in place in the processing and/or distribution of the material?	No	2	Shared or close	3	Yes (Continuous)						
Q10. Are effective measures in place to identify, prevent or minimize the presence of other allergenic materials (crop, risk and other) in the commodity being purchased (due to effectiveness in cleaning, storage, separation)?	Yes	2	Partially	3	No (Continuous)						
Q11. Has allergen analysis been conducted on the allergen of concern for this commodity?	Yes (GFS)	2	No (GFS)	3							
Q12. Has testing been performed by an ISO 17025 accredited laboratory?	Yes	2	No	3							
Q13. Has the commodity undergone a robust validation for stability, for the commodity used? (See Allergen Bureau Data Allergen Control Response)	Yes	2	No	3							
Q14. Is the commodity vulnerable to the release of unprocessed allergen due to storage methods or contamination?	No	2	Yes	3							
Q15. How have you managed any previous instances of allergen cross contact and allergen detection?	Not Reported	2	Yes	3							
Q16. If 'No', did the supplier successfully address the previous instances of cross contact?	Not Reported	2	Yes	3							
Q17. Do you have a supplier farm assessment and contractualized any changes in the supply chain?	Yes	2	No	3							
Q18. Are there any allergen 'free list' claims associated with the purchase of this raw material?	Yes	2	No	3							
Q19. What is the form of the material received?	Quantity (kg/tonnes)	2	Particulates	3							
Q20. What is the expected form of the cross contact allergen in the material?	Quantity (kg/tonnes)	2	Particulates	3							
<b>Total</b>	<b>0</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>0</b>	<b>25</b>					

# What do we know about Agricultural Co-Mingling?



- Agricultural practices are unlikely to change, however GAP are encouraged
- Industry requires a way in which to identify and manage the presence and prevalence of potential allergen cross contact

# Why was the Resource Needed?



The two key questions that required answering are:

1. How do you obtain accurate information?
2. How do you use the information once you have it?

# The Resource Provides Guidance on:

1. Agricultural co-mingling
  - a) Information on cross contact allergens associated with crops and commodities
  - b) Agricultural practices and controls
2. Ingredient questionnaire
3. Risk rating matrix and recommended sample numbers
4. Sample collection, volume, frequency
5. Allergen analysis recommendations
6. Intended use of the outcomes of analysis
7. Case studies



# Business Impacts to Consider

- Supply chains are complex and uncontrollable
- Risks still require identification
- Unexpected allergen presence occurs due to:
  - Intentional addition (VACCP) or;
  - Unintentional / accidental – adventitious presence
- Due diligence must always be demonstrated, even when it's hard
  - “applying all practicable measures”
- Brand and reputation damage
- Recalls cost \$\$



**PRODUCT RECALL**



**Designed to  
integrate with,  
and inform other  
existing programs**

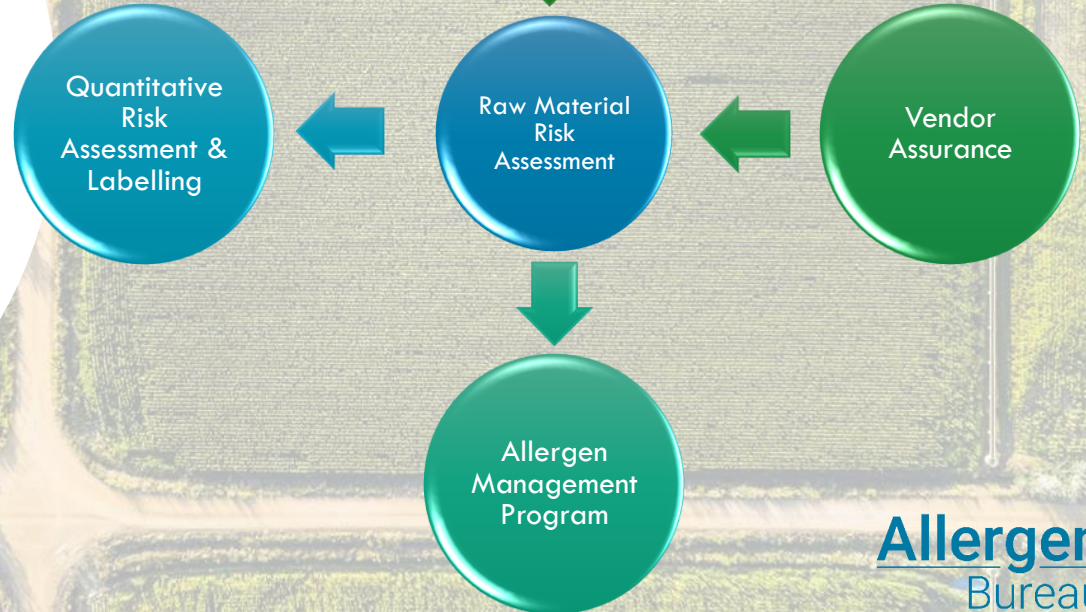


Table 2: Allergens associated with agricultural co-mingling

Food	Details
Cereal Grains (e.g. barley, buckwheat, maize, millet, oats, popcorn, rice, rye, sorghum, spelt, triticale, wheat, wild rice)	<p>Are there any <b>wheat, barley, oats, spelt, lupin</b> or soy crops grown in the same geographical region?</p> <p>What other crops are used for crop rotation by the grower (e.g. <b>lupin</b> and <b>oats</b> can be used in crop rotation)?</p> <p>What other crops are being (or can be) grown nearby? This includes <b>lupin, soy</b> and cereals containing gluten including <b>wheat, wild wheat, barley, spelt</b> and <b>oats</b>.</p> <p>Is the allergen similar in size and colour as the cereal grain (i.e. difficult to clean and separate)? What is the form of the cereal (e.g. whole, split, grits, husked)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? Is the cross contact similar in appearance to the cereal (i.e. difficult to clean and separate)?</p> <p>Examples of known cross contact: -</p> <ul style="list-style-type: none"><li>• <b>Oats</b> with <b>lupin</b> cross contact.</li><li>• <b>Wheat</b> with <b>soy</b> cross contact.</li><li>• Buckwheat kernel with <b>wheat</b> cross contact.</li><li>• <b>Wheat</b> with mustard cross contact.</li></ul> <p>Does the primary and secondary processor have allergen controls within their facility?</p> <p>What effective measures are in place to minimise potential allergen cross contact from shared storage equipment and facilities and/or transportation?</p> <p>What effective separation processes are used by the primary and secondary processors?</p> <p>Example of known cross contact: -</p> <ul style="list-style-type: none"><li>• Sorting facilities for dried corn (such as popcorn) can be shared with <b>wheat, soy</b> etc.</li></ul>

Oil Seeds (e.g. chia seed, hemp seed, linseed, mustard seed, poppy seed, quinoa seed, sesame seed, sunflower seed)

Are any **wheat, sesame** or **soy** crops grown in the same geographical region?

What other crops are being (or can be) grown nearby?

Examples of known cross contact: -

- Chia seed with **soy** cross contact.
- Hemp seed with **wheat** grain cross contact.
- Hemp protein with **wheat** cross contact.
- Mustard seed with **wheat** grain cross contact.

# Overview Of The Risk Assessment Steps

Use the guide, supplier and raw material information complete the Raw Material Risk Matrix Questionnaire

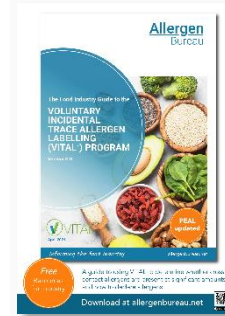
Determine the risk rating:  
Low  
Medium  
High

Use sampling guidance to collect the number of samples required

Conduct allergen analysis, review results, determine presence and prevalence

Use the outcome to inform your Allergen Management Plan and Quantitative Risk Assessment

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# Raw Material Risk Matrix Questionnaire



Risk Assessment Questions		Response Options					
		Lower Risk				Higher Risk	
Q1	Is the material procured from an equivalent regulatory jurisdiction?	Yes	1			No	5
Q2	Does the supply chain include growers or processors from international sources?	No	1	single international source only	3	multiple international sources (grows and/or processors)	7
Q3	Is the supplier GFSI certified?	Yes	1			No	4
Q4	Does the supplier have a documented and robust allergen management plan?	Yes	1			No	7
Q5	Does your business have a detailed understanding and traceability of the agricultural supply chain (i.e. Crop rotation, potential cross contact risk due to shared equipment, storage, transport, sourcing and trading etc)	Yes				No	31
		Go to Q6				Skip to Q10	
Q6	Are other allergenic crops used in crop rotation or grown in close proximity?	No	1			Yes	6
Q7	How is the commodity traded / sourced?	Controlled backward integration programs	1	Contracted farms	3	General markets with lesser known controls	6
Q8	Are effective measures in place to prevent or minimise potential allergen cross contact from shared equipment and facilities throughout the supply chain?	Yes	1	Partially	4	No / Unknown	7
Q9	Are there primary and secondary processors involved in the processing and/or manufacture of the material?	No	1	Some of the time	3	Yes / Unknown	5
Q10	Are effective measures in place to identify, prevent or minimise the presence of other allergenic materials similar in size and colour as the commodity being purchased (due to difficulties in cleaning and/or separation)?	Yes	1	Partially	4	No / Unknown	7
Q11	Has allergen analysis been conducted on the allergen of concern for this commodity?	Yes	1			No	11
		Go to Q12				Skip to Q14	



# Sampling Guidance

Risk Rating	Number of Samples	Supporting Standards
Low	5	EN ISO 948:2009 Spices and condiments Sampling <sup>8</sup>
Medium	Minimum 10. Square root of consignment (if above 100 units)	USFDA Investigations Operations Manual 2020 Chapter 4 – Sampling section 4.3.7.2 Random Sampling <sup>12</sup> EN ISO 948:2009 Spices and condiments Sampling <sup>8</sup> DS/CEN/TS 15568 2007 Foodstuffs - Methods of analysis for the detection of GMO and derived products - Sampling strategies, Section 7 <sup>7</sup>
High	Minimum 15. 10 % of consignment (if above 150 units)	Codex CAC/GL 50- 2004, Table 8, page 34 based on the ICMFS Micro sampling guides <sup>9</sup> EN ISO 948:2009 Spices and condiments Sampling <sup>8</sup> DS/CEN/TS 15568 2007 Foodstuffs - Methods of analysis for the detection of GMO and derived products - Sampling strategies, Section 7 <sup>7</sup>

How were the sample numbers decided?

- Review of current sampling standards for commodities
- No sampling plans for allergens in commodities
- All sampling plans for commodities assume homogeneity
  - Sample numbers decrease the larger the lot size
- Required a “sweet spot”
  - Enough samples to give confidence in determining prevalence
  - Acceptable cost to industry

# Sampling Considerations

- Sampling approach recommended is random to encourage non-biased sampling
- Recognises allergen presence is not always homogeneous
- Includes the recommendation to use visual inspection of the material in addition to analytical analysis
- Sample collection – dependant on the consignment (stream sampling, probes, or automatic sampling)
- For static sampling – use a probe to allow for cross sectional sampling
- Sample volume is recommended



# Presence and Prevalence

## Presence

- Considers the form of the allergen
- Allergen detectability
  - visual and or analytical

## Prevalence

- How often can you detect the allergen in the number of samples analysed?
- Informs the level of risk introduced into the facility



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## UNEXPECTED ALLERGENS IN FOOD

Revised & updated  
August 2022

Informing the food industry

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

Free  
Resources  
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Essential  
allergen guidance  
for those involved in  
Vendor Assurance,  
Raw Material  
Approval & NPD

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**Table 1: Unexpected allergens associated with foods and ingredients**

Food	Details
Soy Sauce	Does it contain <b>wheat</b> (in addition to <b>soy</b> )?
Spice extract(s)	Do they contain any bases, carriers, anti-caking agents (e.g. maltodextrin, flour, oleoresins, emulsifiers)? If yes, what are they derived from (e.g. <b>wheat</b> , maize, <b>soy</b> , <b>egg</b> etc.)?
Spice(s)	Do they contain any bases, carriers, anti-caking agents (e.g. maltodextrin, flour, oleoresins, emulsifiers)? If yes, what are they derived from (e.g. <b>wheat</b> , maize, <b>soy</b> , <b>egg</b> )? Refer to Table 2 (Allergens associated with agricultural co-mingling).
Stabilisers	What are they derived from (e.g. <b>soy</b> , <b>egg</b> , cereals containing <b>gluten</b> )?

Examples provided by industry, for industry

**Table 2: Allergens associated with agricultural co-mingling**

Food	Details
Dehydrated garlic	<p>What is the geographical origin of the garlic? Refer to Case study - Crop rotation practices can impact upon ingredient allergen status.</p> <p>What other crops are used for crop rotation by the grower? Does the farming source crop rotate with <b>peanut</b>?</p> <p>What other crops are being (or can be) grown nearby?</p> <p>What crop measures are in place to effectively remove physical remains of other crops?</p> <p>How is the garlic (fresh or dehydrated) traded/sourced (e.g. through general markets with lesser known controls; contracted farms; controlled Backward Integration programs)?</p>

# Case Study: Unexpected peanut in cashews



Free From Gluten Dairy Free Chocolate Cheesecake 675g

Woolworths Ltd



Sacila brand Pesto 190g

Conga Foods



Jamie Oliver Green Pesto 190g

Woolworths Ltd



Coles Italia Pesto Al Basilico Basil Pesto

Coles Supermarkets Australia Pty Ltd



Black Swan crafted basil dip with cashews and parmesan 200g

Monde Nissin Australia Pty Ltd (Black Swan Foods)



Simplot Leggo's Basil Pesto 190g, Sundried Tomato Pesto 190g, Chicken Tonight Cashew Satay Cooking Sauce 500g <sup>6/02/2020</sup>

Simplot Australia Pty Ltd



Woolworths Italian Style Basil Pesto 190g <sup>6/02/2020</sup>

Woolworths

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## Case Study 2: Supply chains can be complex and need to be fully understood

### Responding to a new allergen cross contact discovery

During December 2019 and January 2020, pesto products manufactured in Italy were recalled across Europe and the UK due to the presence of undeclared peanut. Investigations indicated that the source of the peanut was from cashew ingredients in the form of meal, flour and pieces and it was thought these ingredients originated from Vietnam. In Australia, recalls were instigated for imported pesto products, followed by other products after proactive analysis for peanut in cashew ingredients was carried out. The food industry acted quickly and collaboratively with consumer groups, analytical laboratories, retailers, and regulators, to gain a better understanding of the nature of the issue.

### The investigation begins

Many of the recalled foods were produced in different countries, so it was quickly agreed that the source of the peanut was not where the finished goods were manufactured. Analysis did not provide much insight as it did not show a consistent presence of peanut in the foods. Initially, there was a strong indication that the exposure to peanut occurred due to the bags used to transport the cashews from India and the Ivory Coast to Vietnam where the majority of the cashews are processed. This was uncertain, however, so it was necessary for industry to track back, share knowledge, work together and understand the supply chain to identify the point of exposure.

### Supply chains can be complex

Cashews are grown in many geographical regions worldwide, including Vietnam, India, West Africa, and South America<sup>1</sup>. Most of the whole cashews (the nut within its shell) are then transported to Vietnam for processing.

In cashew processing, the first step is to remove the shell, which is a critical step because the shell is toxic. The shell separation process involves roasting and steaming at high temperatures, and once the shell is removed there is further roasting to remove any residual oils (which may also contain toxins) and peel from the nut. It was concluded that if the unprocessed cashew nuts were exposed to peanut residue from shared bags used during transportation, it is unlikely that peanut residue would remain after the shell, oil and peel separation steps, and any peanut residue present would be much lower than the levels detected in the recalled foods.

The roasted cashews are then graded. The bigger whole nuts are separated from the smaller whole nuts and from the pieces and all are bagged. At this stage, the original shipping bags cannot be reused so as to avoid contamination of the shell toxins.

Whole cashews are considered a premium product and once bagged, are distributed across the world demanding a higher price. During this investigation, analysis in Australia did not detect any peanut residue on whole cashews so the focus was directed to the smaller nuts and pieces.

The smaller whole cashews and pieces can undergo further processing. Some are bagged and distributed to suppliers, but most go on to various processors in the supply chain for additional roasting/nibbling/chopping. The complexity of the supply chain is shown at this point where in Vietnam alone, there are approximately one thousand (large, medium, and small) cashew processing sites. The potential that some of these sites are also processing other tree nuts and peanuts is high. It is likely that some supplier approval systems have not encompassed the complexity of this step.

### Investigation is continuing

It is most likely that the source of the peanut contamination occurred during the secondary processing steps. This aligns with detecting peanut residues in the more finely ground cashew materials and may also explain why analysis did not show peanut consistently present in the foods. Investigation is continuing, however, this case study shows that for commodity ingredients, any secondary processing steps can inherently increase the allergen cross contact risk if allergen management practices are not well understood or implemented. As part of the raw material approval process, the supply chain needs to be fully understood to be confident of the allergen status of ingredients.

# 2019/20 Peanuts in Cashews

- International recalls commenced in Europe & UK in Pesto products
- Only value added (flour, meal and pieces)
- Intentional verses adventitious presence??
- Public health was a risk – consumer reactions reported
- Industry were challenged in the variables
  - Variable levels in the ingredient
  - Test methods varied globally
  - Sampling approaches varied
  - The supply chain was not understood



## Allergen Testing - Special Interest Group (AT-SIG) Briefing Note

### Undeclared peanuts in pests – analytical testing considerations (Version 1.0. Date issued – 07 February 2020)

The Allergen Testing - Special Interest Group (AT-SIG) is a collaborative initiative of the Allergen Bureau and the National Measurement Institute (NMI) that aims to provide coordinated advice on food allergen analysis and testing within Australia.

Since January 2020, there have been several pesto products recalled from the Australian market due to the presence of undeclared peanut. To date, all have been imported product. Food Standards Australia New Zealand released an advisory statement on the 5 February 2020 with further information about these recalls. For more details, refer to [this link](#).

The Australian recalls are related to numerous recalls which have occurred in Europe and the UK during December 2019 and January 2020. For specific information on the recalled international products refer to the [Food Standards Agency website](#).

In recall situations such as these, analytical testing plays a major role in food industry business decisions. The Australian food industry have asked AT-SIG to provide some analytical testing guidance on elements that require consideration when testing for these type of products.

Detailed testing and analytical considerations are available on the Allergen Bureau website on the [Food Allergen Analysis webpage](#).

A brief summary of key information from the Food Allergen Analysis webpage is provided here.

#### Sampling Plan

In cases where the presence of unexpected allergens in products occurs, it is recommended that decisions are not based on a single sample, especially in instances where cross contact may be particulate in nature and when the cause of the cross contact has not been determined. An appropriate sampling plan should reflect the size of the batch produced and aim to inform the level of contamination and the way in which cross contact could have occurred.

Where possible, samples from throughout the process, including raw materials / ingredients should be analysed to help further inform the investigation.

Further information on what to ask the laboratory can be found on the Allergen Bureau Food Allergen Analysis webpage in the [Sampling Plan](#) information.

#### Methods and test kits

It is recommended that (where possible) a validated method be used for determination of the presence of the allergen. The laboratory should be able to advise:

- If the method is appropriate (verified or validated) for the matrix or similar product components.
- What experience they have in the method and the matrix being analysed
- The sensitivity of the method and potential cross reactivities

#### AT-SIG Briefing Note

Undeclared peanuts in pests – analytical testing considerations (Version 1.0. Date issued – 07 February 2020)

#### ELISA technology

In instances such as these it is important that a broadly accepted, internationally recognised methodology is applied for the analysis of allergens in food. Currently ELISA (Enzyme Linked Immunosorbent Assay) remains the internationally accepted and most commonly applied method for the routine detection of allergens in foods. ELISA methods have the advantage of targeting and detecting proteins (usually the allergenic ones) directly.

It is acknowledged that all methodologies have limitations, and those associated with ELISA include cross reactivity and matrix interference, which can lead to false positive or false negative results. Many ELISA kits on the market currently are suitable for the detection of peanut in cashew products and as per kit manufacturers validation documents, do not show cross reactivity between cashew and peanut.

#### Alternative methodologies

**Polymerase Chain reaction (PCR)** methods detect DNA sequences of the allergenic species, not the allergenic protein. They are specific, sensitive, qualitative, can verify or clarify an ELISA result and can detect potentially allergenic products for which no ELISA test is currently available. However, like all detection methods there are limitations including the impact of food processing. Some processing methods can destroy detectable DNA, causing false negative results and food matrices may interfere in the assays. DNA methods are not suitable for the detection of certain allergens, where there are low levels of DNA e.g. egg and milk. PCR methods for allergen detection also have an issue discriminating between different products from the same species, as for example, eggs and chicken contain the same genetic material.

**Mass Spectrometry** has been used in some situations where a clear result from immunoassay and or PCR has not provided clarity however this method is still considered a confirmatory technique rather than a one used for routine screening.

Currently there are no commercial laboratories that are NATA accredited for the analysis of allergens by PCR or Mass Spectrometry in Australia. In the event that verification of a result is required, there is a range of approaches that may be adopted by laboratories including a review of validation data, exclusion of cross reactivity by laboratory investigation and analysis of the sample with an alternate ELISA calibrated against a different range of antibodies.

While allergen analysis continues to improve exponentially, it is important to be aware there is currently no one stand-alone method that can be used for all allergen analyses in all sample types and that analytical results need to be considered in the context of the allergen, matrix, method and production history. Analysis remains a single tool in the determination of allergen risk to a product and should be used in conjunction with a robust risk assessment.

This document is intended to provide an overview of the current methods available in the Australian sector for the analysis of allergens in foods. For specific analytical questions relating to the suitability of methods for your products we recommend that, in the first instance, businesses contact their laboratory service provider.

For guidance on the application of analytical results with respect to a VITAL risk assessment, contact the Allergen Bureau Helpline Services - 0437 918 959 or [info@allergenbureau.net](mailto:info@allergenbureau.net)

#### AT-SIG Briefing Note

Undeclared peanuts in pests – analytical testing considerations (Version 1.0. Date issued – 07 February 2020)

Briefing note  
provided by ATSIG  
7<sup>th</sup> February 2020



**Analysis and results are always in question!**

# ATSIG Meeting held 26<sup>th</sup> February 2020

- Update on the situation at the time
- Analysis considerations
  - LFDs and PCR
- Sampling plans
- Previous incidents and do they provide some direction?
- Feedback provided to the FSANZ incidence group
- Chatham house rules apply



# Outcome?

- Knowledge sharing highlighted the complexity in the supply chain
- Several supply chains involved
- Industry aligned questioning to determine risk potential
- Directions on raw material assessment
  - Value Added verses Whole
- Changes to screening and acceptance testing
- 2021 cashews from the implicated batch were still in circulation

**AND**

**The true root cause still remains unknown**

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*“We can only do what we do  
because of our members financial  
support”*

The new Assessing Agricultural Cross Contact 2022 Guide is a perfect example of how we use these resources to develop tools for the benefit of the whole industry.

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# THANK YOU

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

CONTACT US:



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

[@allergenbureau](#)