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Agricultural Cross Contact

The new resources, their development and use

Informing the food industry

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Allergen Bureau Webinar
5th October 2022

Agenda

- A brief background on the project
- An overview of the new resources
- Risk Matrix – worked practical examples
- Q & A session

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- 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

THE COCA-COLA COMPANY

Full Members

- ALDI Stores
- BBF Hull Limited

What is Agricultural Co-Mingling?

Agricultural co-mingling is the result of different crops being grown in proximity with each other, sharing the same fields due to crop rotation, and/or sharing the same equipment/facilities for harvesting, transport, and storage, despite the application of allergen controls as part of Good Agricultural Practices (GAPs).

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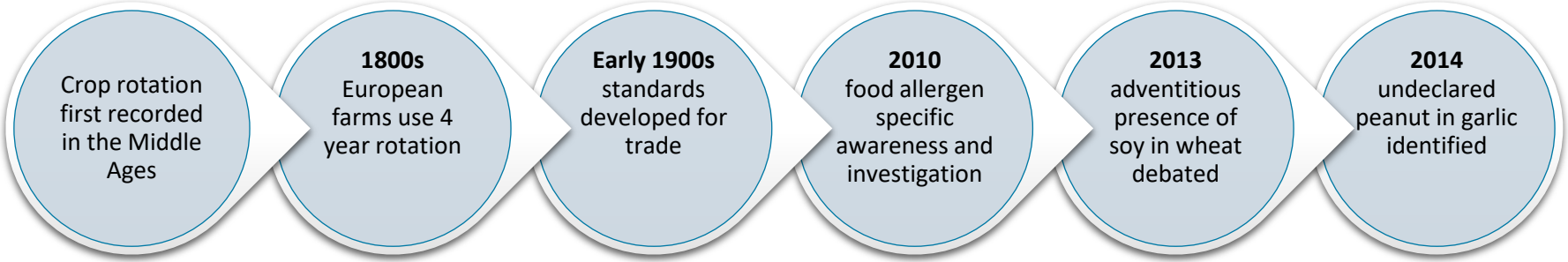
What do we know about Agricultural Co-Mingling?



- 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

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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?

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Unpacking the Peanut in Garlic?

- Why were undeclared allergens present
  - Varied geographical locations
  - Only value added
  - Intentional verses adventitious presence??
- What was the public health risk?
- How does industry assess the risk?
  - Variable levels in the ingredient
  - Was it particulate?
  - What the risk in the finished product?
- Is the testing accurate?
- How extensive is this issue in other commodities?
- Peanut free garlic?

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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
- Standardised industry guidance was required!

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How is Peanut in Soy Lecithin Different in 2022?

- Peanut identified in soy lecithin from India (April 2022)
- Possible cause identified at the mill
- Variable levels on peanut detected
- Ingredient is generally used in a small percentage
- Food authorities advise to increase surveillance testing, and conduct a finished product risk assessment

https://www.greatitalianfoodtrade.it/en/sicurezza/rasff-arachidi-nella-lecitina-di-soia-dallindia-analisi-del-rischio/

https://www.foodsafetynews.com/2022/08/uk-agencies-urge-testing-of-soy-product-from-india-because-of-peanut-risk/

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The Allergen Bureau's Agricultural Co-Mingling Working Group has been committed to producing practical guidance to assist industry to identify and manage agricultural cross contact risk.

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Who Is The Guide For?

Relevant to all areas of the food industry the new guide will be a useful tool for

- growers,
- primary producers,
- food ingredient manufacturers, importers,
- suppliers,
- food business operators (FBO's),
- importers of packaged foods.

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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 used of the outcomes of analysis
7. Case studies

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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 $$

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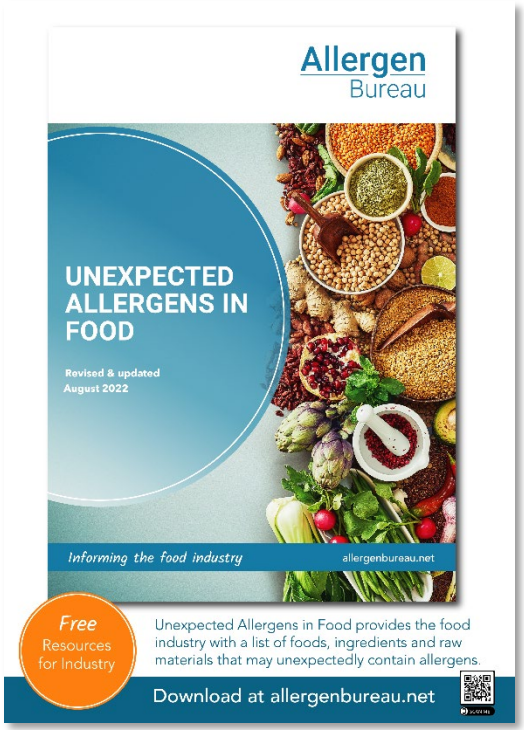
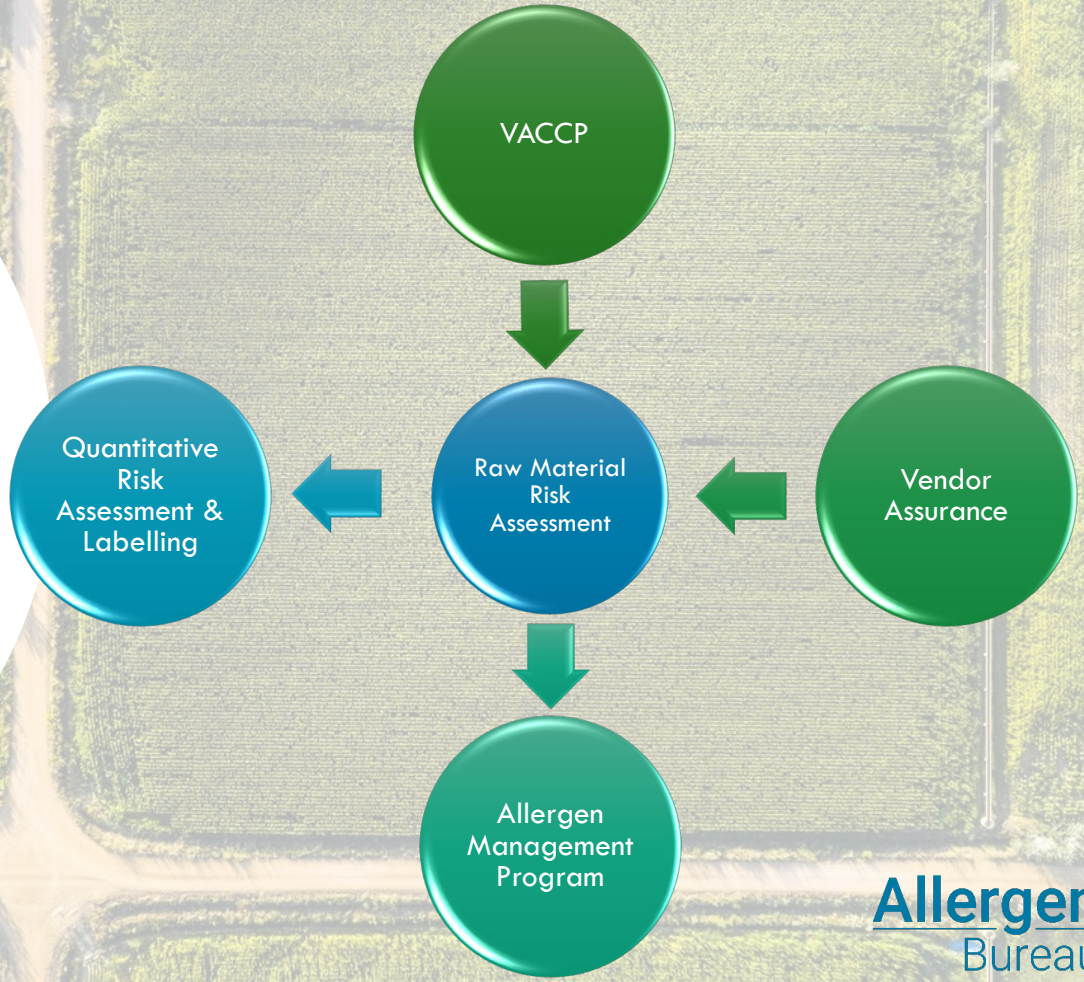
Resources Available



Designed to integrate with, and inform other existing programs



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Overview Of The Risk Assessment Steps

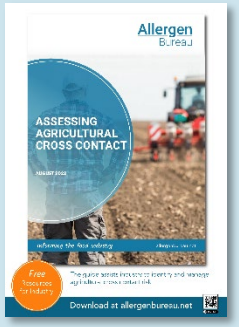
Use the guide, supplier and raw material information complete the Raw Material Risk Matrix Questionnaire

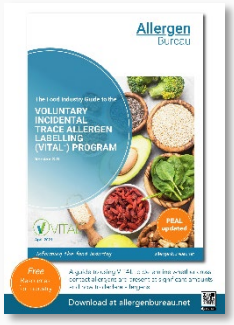
Determine the risk rating:
Low
Medium
High

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

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Reset Questionnaire

Risk Assessment Questions		Response Options					
		Lower Risk				*Higher Risk*	
Q1	Is the material procured from an equivalent regulatory jursidiction?	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 tracebility of the agricultural supply chain (i.e Crop rotation, potential cross contact risk due to shared equipment, storage, transport, sourcing and trading etc)	Yes *Go to Q6*				No *Skip to Q10*	31
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 *Go to Q12*	1			No *Skip to Q14*	11

Sampling Guidance

Risk Rating	Number of Samples	Supporting Standards
Low	5	EN ISO 948:2009 Spices and condiments Sampling[8]
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[12] EN ISO 948:2009 Spices and condiments Sampling[8] DS/CEN/TS 15568 2007 Foodstuffs – Methods of analysis for the detection of GMO and derived products – Sampling strategies, Section 7[7]
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[9] EN ISO 948:2009 Spices and condiments Sampling[8] DS/CEN/TS 15568 2007 Foodstuffs – Methods of analysis for the detection of GMO and derived products – Sampling strategies, Section 7[7]

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

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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

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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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Application of the Risk Assessment Outcomes

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1. Raw material

- Information may be difficult to obtain
- Lacking information results is a higher risk rating outcome
- Risk reduction strategies can be implemented when gaps are identified
- Detection of allergens through analysis and or visual assessment informs allergen management practices

VACCP

Vendor Assurance

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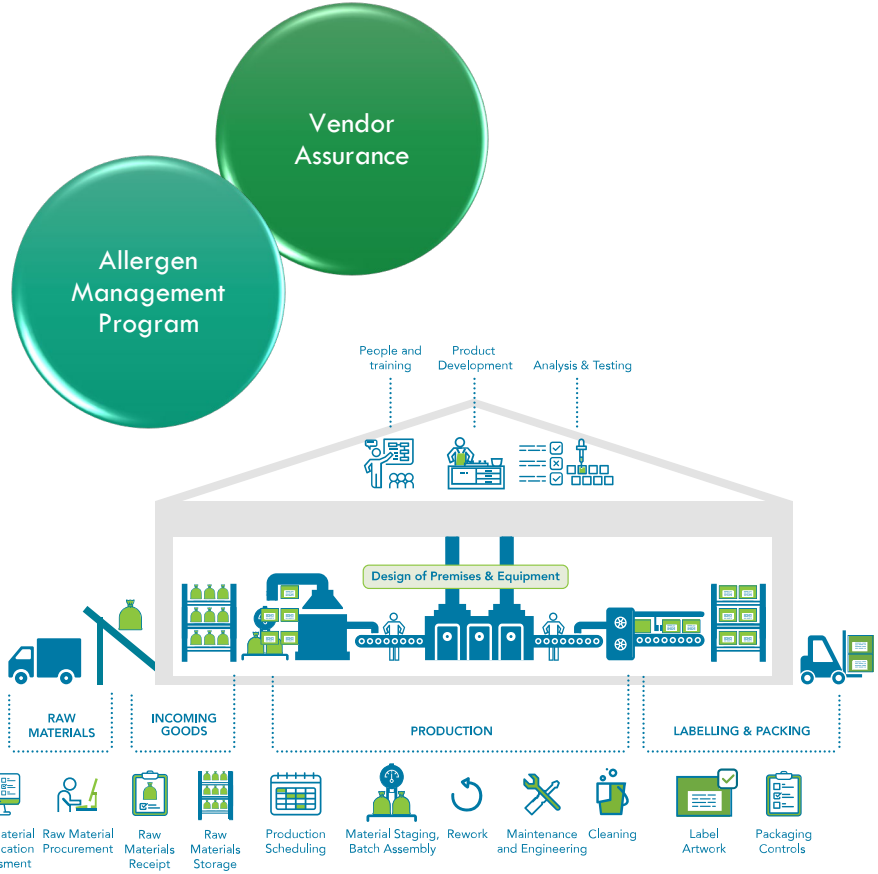
2. Allergen Management

Determining **presence and prevalence** of the allergen in the material:

- Informs the allergen risk profile in the facility
- Informs AMP procedures
  - Material handling procedures
  - Production scheduling
  - Cleaning



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3. VITAL® 3.0 Risk Assessment

- Identifies the form of the ingredient cross contact
- Allows the business to assess further processing impacts (milling, grinding, etc)
- Analysis informs variability of presence and prevalence (ppm) and aids in determining likely maximum cross contact levels
- Where assessed agricultural cross contact is determined to be homogeneous, unavoidable and sporadic, this can be used in a VITAL risk assessment

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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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The Sample and Testing Sub-Working Group

- Una Mullany (The Coca Cola Company)
- Rhonda Spyrou (The Kraft Heinz Company)
- Vivienne Balm (The Kraft Heinz Company)
- Dean Clarke (National Measurement Institute)
- Kieran Hopkins (SGS)
- Karl Kusko (ALS Global)
- Joanne Price (HJ Langdon)

We sincerely thank this team for volunteering their time outside of work hours

Joanne Price – HJ Langdon

Worked examples

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Example 1 – Crisis Assessment

- Peanut detections in diced cashew
- Results received show peanut protein detection of 500ppm and 300ppm in Diced Cashews
- The product does not have a risk identified for peanut and the supplier cannot determine immediate cause.
- Processing of whole foreign material including peanut is likely to be in particulate form unless the contamination was in powder form. The supplier cannot help determine a root cause therefore the worse case scenario would be to consider the potential contaminate a particulate.
- The following risk assessment is to determine how many samples to take to confirm through testing a peanut cross contact risk in current stock on hand.

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Example 1 – Risk rating and sampling

Particulate testing

- Supplier Score of 94 = High
- Minimum of 15 samples or 10% of consignment above 150 units
- Cashews are packed 10*2 per box = 20kg

Stock On Hand

- Order 1 = 100 x 10kg packets = 15 random samples
- Order 2 = 400 x 10kg packs = 400 x 10% = 40 random samples

Results

- No detections
- With particulates is this enough alone to suggest there is no cross contact and how do you manage the original high results?

Risk Rating	Number of Samples
Low	5
Medium	Minimum 10. Square root of consignment (if above 100 units)
High	Minimum 15. 10 % of consignment (if above 150 units)

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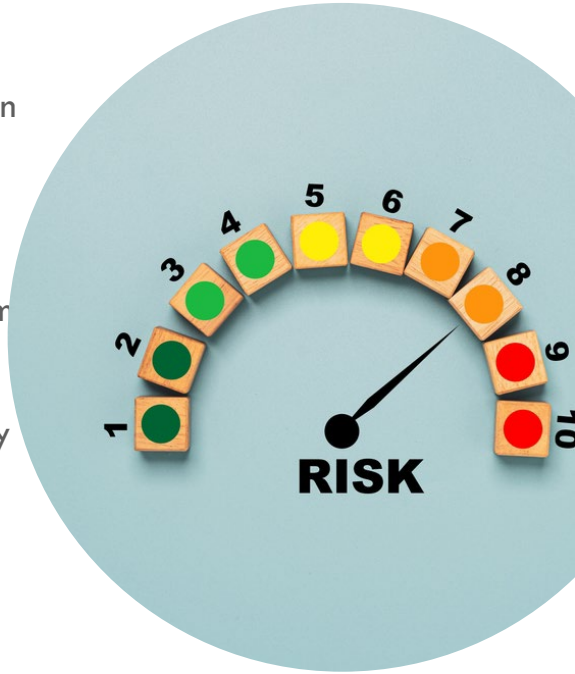
Example 2 – Supplier Validation

- Wheat (gluten) was detected at 28ppm (37.3ppm wheat*), 18ppm (24ppm wheat*) and 10ppm (13ppm wheat*) in a mustard product with a specification of <5ppm gluten. *Conversion from gluten to wheat concentration assuming 75% of all wheat protein is gluten*

- The supplier has worked with their supply chain for mustard seeds to address mitigating wheat cross contact. They identified that cross contact is coming from transportation and storage.

- The Supplier wants our advice as to what sort of testing plan they should carry out to help determine a limit to put on the specification.

- **Objective**: The following risk assessment is determine how many samples to take for validating the control measures implemented by the supplier.



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Note: This example has been updated post the Webinar 5/10/2022

Example 2 – Risk rating and sampling

Sample number determination

- Risk rating of 51 = Medium Risk
- Sampling Minimum of 10 or Square root above 100 units

Choosing samples

Unit size	3500 MT	5000 MT	8000 MT	10,000 MT
Bags	= √ 140 bags =11.8	= √200 = 14	=√ 320 = 17.8	= √400 = 20
Pallets	= 2.54 pallets Minimum 10 samples	= 3.6 pallets	=5.8 pallets	= 7.2 pallets
Volume/ kg produced	3500/10 = 350kg	5000/10=500kg	8000/10=800kg	10,000/10=1000kg

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Example 2 – Testing outcome

Results

- 9,625 kg = 385 bags (20 samples) OR 7 pallets (Minimum of 10 samples)
- Samples taken per 960kg produced.
- <20 mg/kg Gluten (12 samples)
- Supplier sets a limit of 20ppm gluten for screening purposes (equals 27ppm wheat protein)

9.9 PPM	6.4 PPM	5.1 PPM	<5.0 PPM	<5.0 PPM	<5.0 PPM
<5.0 PPM	<5.0 PPM	<5.0 PPM	<5.0 PPM	<5.0 PPM	<5.0 PPM

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Example 2 – Validation acceptance and next steps

Can we accept this data as supporting validation data?

- Which sampling plan would provide you with stronger data?
- Production runs what are the average run sizes and does this sampling cover it?
- How many times do you need this repeated?
- Across how many products?
- What can you afford? What can you supplier afford?
- What risk level are you prepared to accept?

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Example 3 – Ongoing Verification

Wheat in Mustard

- Agricultural cross contact for wheat occurs during transportation and storage
- The supplier has worked with their supply chain for mustard seeds to address mitigating wheat cross contact
- Validation testing over three consecutive production runs across 3 different product sku's was completed to assess the effectiveness of the control
- The validation risk assessment identified a specification for gluten content will not exceed 20ppm
- The following risk assessment is to determine how many samples to taken for end customer verification.

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Example 3 – Risk rating, sampling, outcome

Sample number determination

- Supplier Score 34 = Low
- 5 samples

Choosing samples and results

- Mustard is supplied in 25kg bags, 1000kg per pallet
- 6000kg, 240bags, 6 pallets

<5.0ppm	<5.0ppm	<5.0ppm	<5.0ppm	<5.0ppm

- 2000kg, 80bags, 2 pallets

<5.0ppm	<5.0ppm	<5.0ppm	<5.0ppm	<5.0ppm

Risk Rating	Number of Samples
Low	5
Medium	Minimum 10. Square root of consignment (if above 100 units)
High	Minimum 15. 10 % of consignment (if above 150 units)

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How this relates to the VITAL ® Program

- The VITAL Program helps to answer "**is the amount of wheat in the mustard flour significant?**"
- **Reference Dose = 0.7 mg** of wheat protein
- If a sensitive person eats LESS THAN 0.7 mg of wheat protein, it is unlikely that they will have an adverse reaction
- For the Mustard Flour example, assume that gluten is present at a maximum of 20ppm which is equivalent (in this case) to 27 mg wheat protein per kg
- Amount (g) of Mustard Flour which contains the Reference Dose = (1000*Reference Dose)/Cross Contact (ppm) = (1000*0.7)/27 = 26g
- If a sensitive person eats less than 26g of the Mustard Flour, it is unlikely that they will have an adverse reaction. In the rare case that an adverse reaction occurs, it will be mild, transitory and not require pharmacological intervention.
- A recipe for Mustard, Bacon & Caramelised Onion paleo quiches has 1tsp mustard flour which makes 12 quiches. Assuming 1tps = 5g of mustard flour, then someone would need to each 60 quiches in order to consume the Reference Dose!

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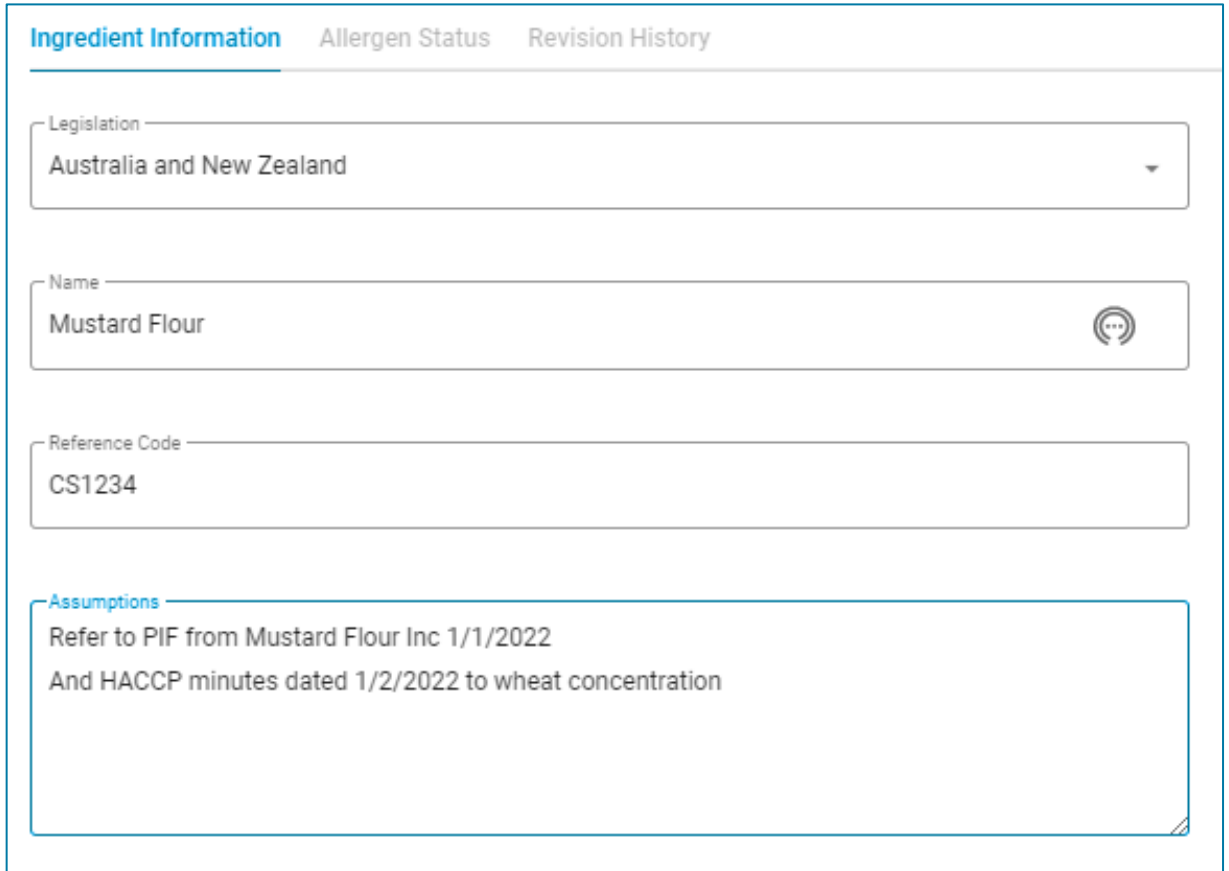
Worked VITAL Example – Mustard Flour

Adding Mustard Flour ingredient to VITAL Online

vital.allergenbureau.net

Step 1:
Ingredient Information



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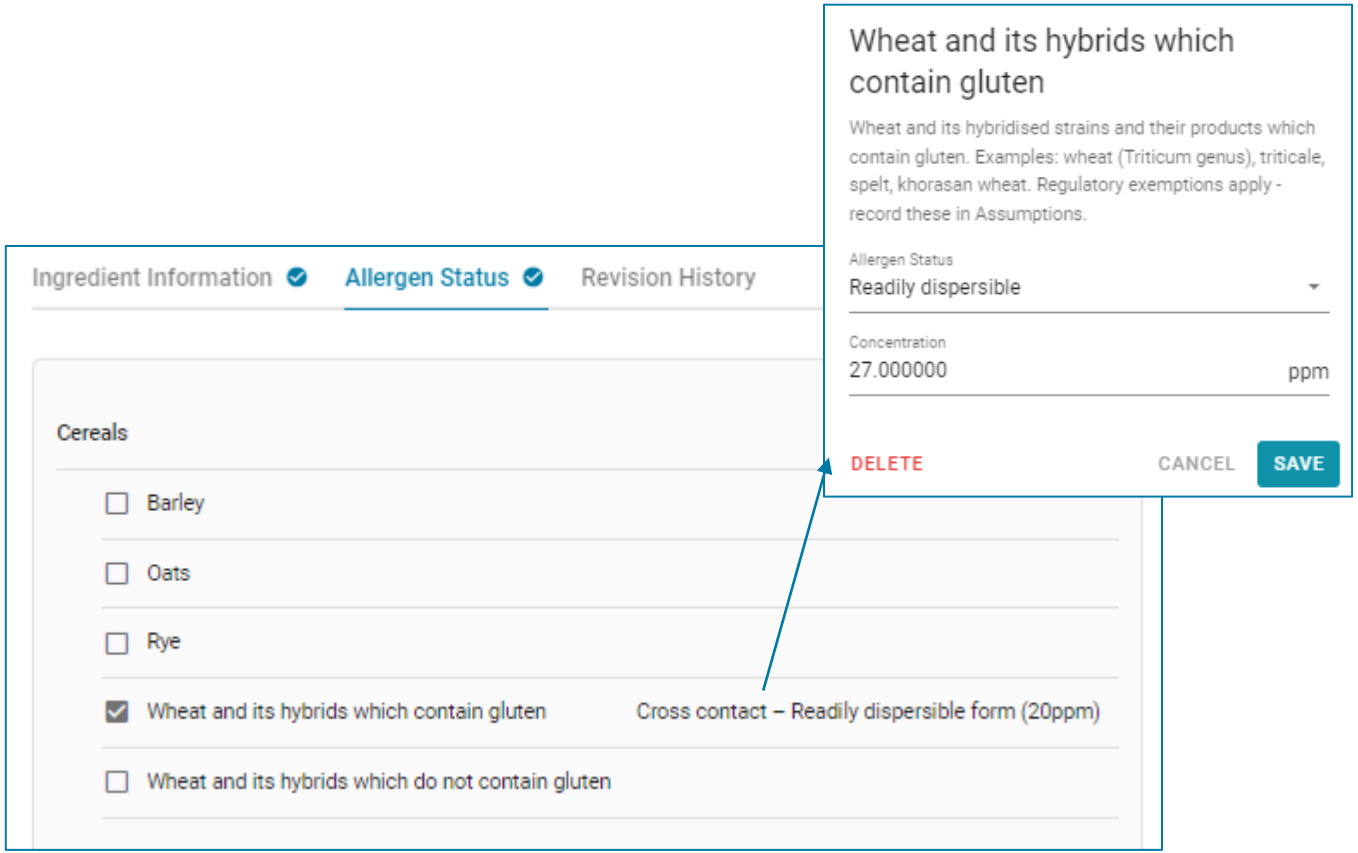
Worked VITAL Example – Mustard Flour

Step 2:

Allergen Status



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Worked VITAL Example – Mustard Flour

Step 3:

Add to a Recipe – contain 3% Mustard Flour

Fish Curry Recipe: Ingredients	Amount (%)	Allergen Status
Mustard Flour	3	27 ppm wheat protein
Other Ingredients	97	Intentionally added: milk, fish

Table 2: Summary of VITAL Assessment for Curry containing mustard Flour (G)

Substance	Action Level 1	Action Level 2	Intentionally Added	Particulate	Readily Dispersible	Labelling Outcome
Cereals (Totals)	< 3.5 ppm	≥ 3.5 ppm	—	—	0.810000 ppm	Action Level 1
Barley	< 3.5 ppm	≥ 3.5 ppm	—	—	—	—
Oats	< 3.5 ppm	≥ 3.5 ppm	—	—	—	—
Rye	< 3.5 ppm	≥ 3.5 ppm	—	—	—	—
Wheat and its hybrids which contain gluten	< 3.5 ppm	≥ 3.5 ppm	—	—	0.810000 ppm	Action Level 1

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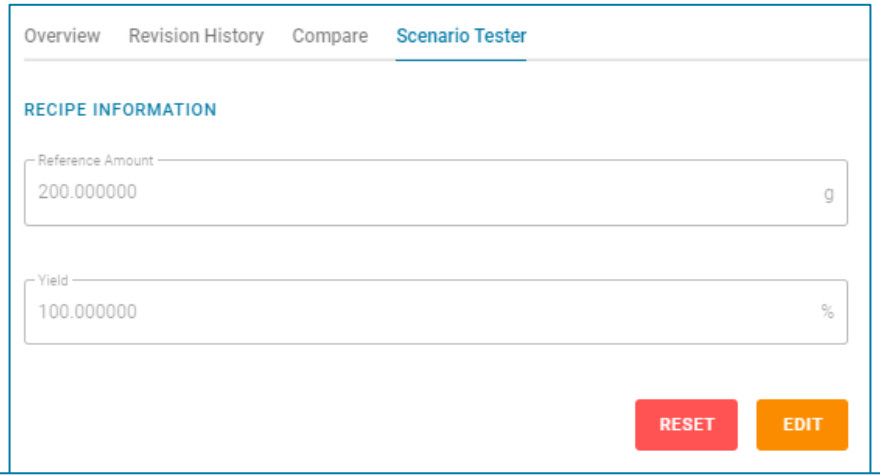
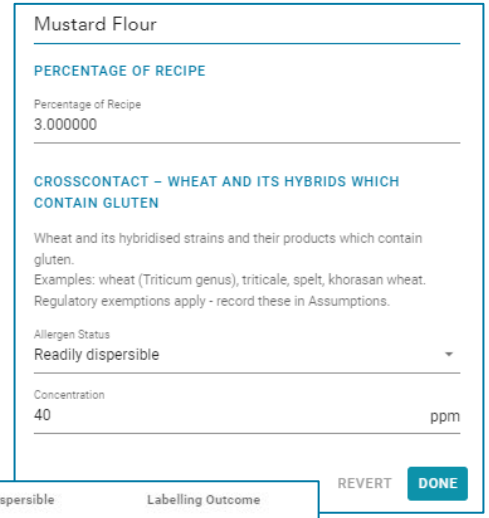
Worked VITAL Example – Mustard Flour

Step 4:

Scenario Tester





Substance	Action Level 1	Action Level 2	Intentionally Added	Particulate	Readily Dispersible	Labelling Outcome
Cereals (Totals)	< 3.5 ppm	≥ 3.5 ppm	—	—	1.200000 ppm	Action Level 1
Cereals (Totals)	< 3.5 ppm	≥ 3.5 ppm	—	—	0.810000 ppm	Action Level 1
Barley	< 3.5 ppm	≥ 3.5 ppm	—	—	—	—
Oats	< 3.5 ppm	≥ 3.5 ppm	—	—	—	—
Rye	< 3.5 ppm	≥ 3.5 ppm	—	—	—	—
Wheat and its hybrids which contain gluten	< 3.5 ppm	≥ 3.5 ppm	—	—	1.200000 ppm	Action Level 1
Wheat and its hybrids which contain gluten	< 3.5 ppm	≥ 3.5 ppm	—	—	0.810000 ppm	Action Level 1

Particulate cross contact & the VITAL Program

- A particulate cross contact is a material that does not mix homogeneously with other parts of the food and/or may consist of, or is likely to aggregate into an entity which contains equal to or greater than the Reference Dose
- **For example: a sesame seed contains the Reference Dose (0.1mg of sesame protein)**
- In the VITAL Program, a particulate results in an Action Level 2 labelling outcome – a PAL statement is required
  May be present: sesame.
- Ingredient suppliers should advise their customers that the product contains a particulate cross contact allergen – and continue to maintain the cross contact at the lowest practicable level in the product

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THANK YOU

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

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