

informing the food industry

Allergy, Allergens & Allergen Management for the Food Industry

Romer Labs – Food Allergen Seminar

January 2018

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The Allergen Bureau

- Established in 2005 due to industry demand, a 'Not for Profit' organisation
- Manage VITAL® Program, continues to invest
 & engage broadly
- Our members steer the resources & projects
 - 31 Full members
 - 23 Associate members
 - 21 Individual members



Our reason for being to share information & experience across the food industry on the management of food allergens to ensure consumers receive relevant, consistent & easy to understand food allergen information



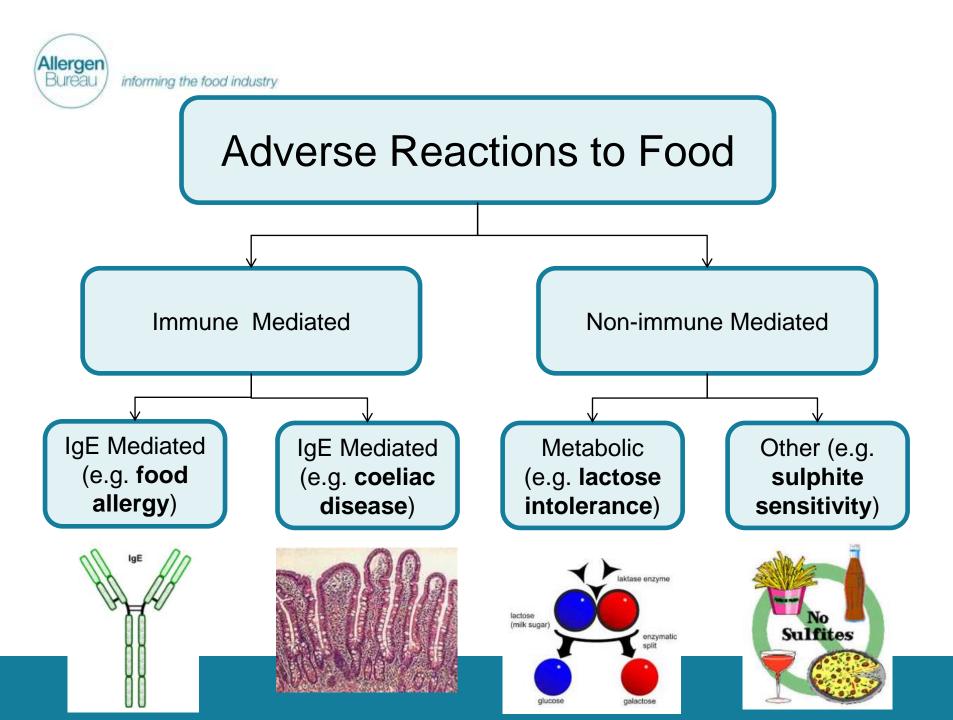
Overview

- Adverse Reactions to food
- Global Allergen Regulations
- Best Industry Practice in Supply Chain, Cleaning
 Validations & Verifications
- ~ Lupin
- ~ The VITAL® Program



Adverse Reactions to Food

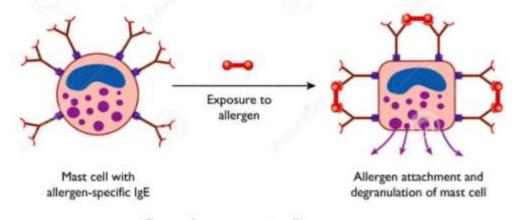






Food allergy

- an abnormal response to a food that is triggered by the immune system (mediated by mast cells)
- the body produces antibodies against the food allergen protein and when it is eaten by the food allergic individual their body will release histamine and other chemicals rapidly causing inflammation





Food allergen

- a normally harmless substance that triggers an allergic reaction
- most food allergens are proteins (an exemption is a sugar molecule which causes mammalian meat allergy)

Some foods contain multiple allergenic proteins – e.g. Milk proteins (Whey fraction and casein fraction). Individual may be allergic to only one milk protein or more.



Predominant food allergens

peanuts crustacea

tree nuts sesame

soy lupin

milk mustard

egg celery

fish

cereals containing gluten





The allergic reaction

- Dermal skin breaks out in hives or eczema
- ~ Gastrointestinal nausea, cramps, diarrhoea
- Respiratory struggle for air
- Circulatory blood pressure drops, lose consciousness

Anaphylaxis is an acute allergic reaction ~ in rare cases, multiple organ systems are affected and death can occur in as little as ten minutes



Some symptoms of an allergic reaction to a food







Urticaria Atopic Dermatitis Anaphylaxis



Coeliac disease

- immune system reacts abnormally to gluten (a protein found in wheat, rye, barley and oats) causing small bowel damage
- a strict, life-long gluten free diet is the only treatment.

Wheat allergy (allergic response to wheat protein) is different to coeliac disease (immune response to gluten proteins)



Food intolerance

Detrimental reaction to food – not a food allergy. Symptoms are generally less serious than true food allergy and often limited to digestive problems.

Lactose intolerance is an example where a person is intolerant to the lactose carbohydrate in milk which is different to an allergy to milk protein



Sulphite intolerance

- sulphites are a family of preservatives permitted for use in some food and drinks.(Additives 220-228)
- sulphite intolerance can trigger asthma symptoms in individuals with underlying asthma.

Wheezing is the most common reaction to sulphites.

In very rare cases however, anaphylaxis can occur.



Impact of food allergy

- there is currently no cure
- sensitivity differs between individuals and depends on type of food, amount ingested and other activities at time of ingestion
- people with food allergy do not know <u>when</u> their next allergic reaction will occur or <u>how severe</u> it will be

Avoidance of the food is the only protection



Food allergy rates are increasing in Australia and New Zealand

food allergy affects*

- ~ 10% infants (up to 12 months old)
- ~ 4-8% children (up to 5 years)
- ~ 2% adults (approx.)

- rapid increase in food allergic disease in last 30 years in mainly the Western world
- 80% of children outgrow milk, egg, soy and wheat allergy by age 5
- individuals allergic to peanuts, tree nuts, sesame or seafood will have this for life



Global Allergen Regulation





Intentionally Added Allergens

- an intrinsic part of the ingredient materials for a product.
- added to foods via ingredients, compound ingredients, additives & processing aids.
- e.g. A muffin with eggs, butter and milk as ingredients, has egg and milk as intentionally added allergens.
- In most jurisdictions, intentionally added allergens are required to be declared on the label.



Unintentionally Added Allergens

- a residue or other trace amount of an allergenic food that is unintentionally incorporated into another food.
- e.g. two products are manufactured on the same equipment and one product may unintentionally become incorporated with another product: if an almond muffin is made on the same line as a chocolate muffin, then almond may be an unintentionally added allergen in the chocolate muffin
- Many regulations are silent on unintentionally added allergens. They are found in precautionary allergen labels (May contain... Etc)



Unintentionally Added Allergens

- many regulations are silent on unintentionally added allergens.
- the subject of precautionary allergen labelling (PAL)
- e.g. May contain, Made on equipment which also makes, May contains traces of ...



How do <u>Un</u>intentionally Added Allergens get into products?

- Shared processing, storage or facilities
- Manufacturing facilities can be complex
- Dry-blend and chocolate very difficult to clean
- Supply chains are complex
- Production Scheduling, Human Error, Rework, Cleaning



1. Mandatory Allergens: What are the allergens required for mandatory declaration? It is likely that consideration of the presence of these allergens through cross contact should also be considered – i.e. These allergens should be controlled in the manufacturing environment. For example: EU includes molluscs, AU/NZ has sesame seeds, Japan has an extensive list, South Africa includes goat's milk.



2. Allergen Definitions: Each allergen may have a different definitions and/or interpretation in each jurisdiction. Look out for cereals containing gluten, fish & tree nuts which are different between major jurisdictions.

E.g. US states "wheat", EU & AU/NZ have "cereals containing gluten"; for tree nuts, US includes "coconut" and this is specifically exempted in AU/NZ. EU industry includes "celeriac" in "celery". AU/NZ includes molluscs with fish.



3. Exemptions to the declaration of mandatory allergens: Glucose syrup is specifically exempted from mandatory declaration in AU/NZ and EU (if it meets certain criteria). Exemptions must be specifically applied for in US.

Ensure that any exemptions used fulfil the appropriate criteria.



4. Requirements for unintentionally added allergens

Where the treatment of cross contact allergens is not mandated, look for industry guidance (e.g. The VITAL Program). Apply GMP & AMP.

AU/NZ regulations are silent on cross contact allergens. "May contain" labelling is specifically prohibited in Japan.



5. "Gluten Free" Claims e.g. In Australia and New Zealand, gluten free claims are regulated.

For a food to carry a gluten free claim it must **not** contain

- Detectable gluten
- Oats or oat products (no gluten free oats)
- Any cereal containing gluten that have been malted, or products of such cereals

In other jurisdictions (EU), gluten free is regulated as <20mg/kg.



6. Industry guidance can be helpful for interpretation (in addition to guides from government agencies)

AU/NZ:

Allergen Bureau <u>www.allergenbureau.net</u>

Australian Food and Grocery Council www.afgc.org.au FU:

Food and Drink Federation www.fdf.org.au and British Retail Constortium & www.brc.org.au

US:

Food Allergy Research and Resource Program https://farrp.unl.edu/



7. Keep up-to-date: change is constant!

Lupin added as a mandatory allergen for AU/NZ. Always check the regulation. Seek advice where required.

Watch recall notices (to understand enforcement decisions).



Mandatory Allergens – Helpful resource!

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FOOD ALLERGENS		USA /	CANADA	(A)	AUSTRA	HONG	CHIMA	JAPAN	408EA	TAIWAN
CRUSTACEAN SHELLFISH	X	X	X	Х	Х	X	Х	Х	Х	х
EGG	X	X	X	Х	Х	X	Х	X	Х	X
FISH	X	X	X	Х	Х	X		Х		X
MILK	X	X	X	Х	Х	X	X	X	X	X
PEANUT	Х	X	X	Х	Х	X	X	X	X	X
SOY	X	X	X	Х	Х	X		X		X
TREE NUTS	X	X	X	Х	Х	×1				X
WHEAT	X	X	X	Х	1	X	X	X		
CEREAL GRAINS W/ GLUTEN		X	X	1	Ä,	X				X
BUCKWHEAT			OX	h.	or		X	X		
CELERY	1		X							
LUPIN	C	1	X	Х						
MOLLUSCAN SHELLFISH		X	X	Х						
MUSTARD		X	X							
SESAME		X	X	Х						
SULFITES	Х	Х	Х	Х	Х					Х
BEE POLLEN/ PROPOLIS				Х						
ROYAL JELLY				Х						

- Allergens in each jurisdiction
- Food Allergy
 Research and
 Resource
 Program –
 University of
 Nebraska-Lincoln
- https://farrp.unl.ed u/IRChart



Some regulations....



Australia and New Zealand Food Standards Code – Standard 1.2.3 & Standard 1.2.7 (Schedule 4) & Standard 1.2.4:

http://www.foodstandards.gov.au/code/Pages/default.aspx

Regulation (EU) No 1169/2011 of the European Parliament – Article 21

http://eur-lex.europa.eu/legalcontent/EN/ALL/?uri=CELEX%3A32011R1169

FALCPA (US) – Section 203

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm



European Union Regulation 1169/2011

Article 9 List of mandatory particulars (1) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form

Article 21 Labelling of certain substances or products causing allergies or intolerances (1a) they shall be indicated in the list of ingredients in accordance with the rules laid down in Article 18(1), with a clear reference to the name of the substance or product as listed in Annex II



EU allergens – refer to EU 1169/2011 for complete information (including exemptions)

Cereals containing gluten: namely wheat (including specific varieties like spelt and Khorasan), rye, barley, oats and their hybridised strains) and products thereof

Crustaceans and products thereof (for example prawns, lobster, crabs and crayfish)

Egg and products thereof

Fish and products thereof

Peanut and products thereof

Soybeans and products thereof

Milk and products thereof (including lactose)

Nuts: namely almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut and Macadamia nut (Queensland nut) and products thereof

Celery and products thereof

Mustard and products thereof

Sesame seeds and products thereof

Sulphur dioxide and sulphites (at concentrations of more than 10mg/kg or 10mg/L in terms of the total SO2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers)

Lupin and products thereof

Molluscs and products thereof (for example clams, oysters, scallops, snails and squid)



FDF/BRC do not the support the use of precautionary allergen labelling – note the labelling below "Also, not suitable for customers with a peanut allergy"

INGREDIENTS: Wheat flour, dried onions, palm oil, dried parsley, skimmed milk powder

Allergy Advice!

For allergens, including cereals containing gluten, see ingredients in **bold**Also, not suitable for customers with peanut allergy



EU Regulations – further references

 Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance

https://www.food.gov.uk/sites/default/files/food-allergen-labelling-technical-guidance.pdf

BRC/FDF industry guide
 http://www.foodlaw.rdg.ac.
 uk/pdf/uk-12024-BRC-FDF
 -Allergen-Labelling.pdf





Australia New Zealand Food Standards Code

Section 1.2.3-4 Mandatory declaration of certain foods or substances in food sets out further requirements for declaring these foods or substances if present in a food.

A declaration is required when these foods or substances may be present as:

- (a) an ingredient or as an ingredient of a compound ingredient; or
- (b) a substance used as a food additive, or an ingredient or component of such a substance; or
- (c) a substance or food used as a processing aid, or an ingredient or component of such a substance or food.



Australia New Zealand Food Standards Code

informing the food industry

1.2.3—4 Mandatory declaration of certain foods or substances in food

- (1) For the labelling provisions, if any of the following foods or substances is present in a food for sale in a manner listed in subsection (2), a declaration that the food or substance is present is required:
 - (a) added sulphites in concentrations of 10 mg/kg or more;
 - (b) any of the following foods, or products of those foods:
 - (i) cereals containing *gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than:
 - (A) where these substances are present in beer and spirits; or
 - (B) glucose syrups that are made from wheat starch and that:
 - (a) have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and
 - (b) have a gluten protein content that does not exceed 20 mg/kg; or
 - (C) alcohol distilled from wheat;
 - (ii) crustacea;
 - (iii) egg;
 - fish, except for isinglass derived from swim bladders and used as a clarifying agent in beer or wine;
 - (v) milk, other than alcohol distilled from whey;
 - (vi) peanuts;
 - (vii) soybeans other than:
 - soybean oil that has been degummed, neutralised, bleached and deodorised; or
 - (B) soybean derivatives that are a tocopherol or a phytosterol;
 - (viii) sesame seeds;
 - (ix) tree nuts, other than coconut from the fruit of the palm Cocos nucifera;
 - (x) lupin.



Recent Changes to FSC Standard 1.2.3: **Lupin**

- Lupin was added to the substances which require mandatory declaration - 25th May 2017
- Transitional arrangement until 25th May 2018 for compliance
- No stock-in-trade provision all products and declarations, including products on shelf, must be compliant by 25th May 2018



Recent Changes to FSC Standard 1.2.3: **Exemptions**

- Exemptions to the requirement for mandatory declaration were added to FSC August 2016
- Glucose syrups made from wheat starch
- Fully refined soy oil
- Soy derivatives (tocopherols and phytosterols)
- Distilled alcohol from wheat or whey



Japan – mandatory allergens

Consumer Affairs Agency, Government of Japan

- Seven allergens for which labelling is mandatory and twenty allergens for which labelling is recommended.
- Labelling Requirement: Egg, Milk, Buckwheat, Wheat, Peanuts, Crab, Shrimp/Prawn
- Recommended: Abalone, Mackerel, Squid, Salmon, Salmon Roe, Cashew Nut, Walnut, Matsutake Mushroom, Sesame, Soybean, Yam, Apple, Banana, Kiwifruit, Orange, Peach, Beef, Chicken, Gelatin, Pork



Japan – Precautionary Allergen Labelling

- The Standard does not permit the use of "may contain" language.
- http://www.caa.go.jp/foods/index18.html.



United States – Spelling differences with UK English!

- Labeling v labelling
- Modernization v modernisation
 - Color v colour
 - Center v centre



United States – Mandatory Allergens

- Food and Drug Administration (FDA) enforces the Federal Food Drug and Cosmetic Act (FD&CA)
- In 2004, the Food Allergen Labeling and Consumer Protection Act (FALCPA) which amended the FD&CA
- FALCPA required sources labelling in the ingredient statement and/or Contains statement
- Priority Allergens: Peanut, Milk, Egg, Tree Nuts, Soybean, Fish, Crustacean Shellfish, and Wheat



United States - definitions

- For tree nuts, fish and crustacean shellfish, the specific species used in the product formulation are required to be specifically labelled (e.g. Cod/tuna fish gelatin or almonds)
- Guidance for "tree nuts" listed 19 tree nuts, including coconut. However, inspectors and auditors have made this the list of tree nuts and recalls have occurred if coconut is not labelled

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm059116.htm



United States - exemptions

- source allergen labelling requirements for highly refined oils are exempt - however, Congress did not define 'highly' refined. (may include RBD oils and NOT cold pressed or extruded oils)
- Industry request exemption to FDA for specific ingredients from allergen labelling requirements. Currently only 2 exemptions which include specific soy lecithin products from Solae and ADM. The exemption only applies when these soy lecithin products are used as a release agent AND when applied directly to the contact surface.



United States – gluten free

- The FDA adopted the Codex recommendation
 ≤20 ppm gluten for gluten free labelling in 2013
- It does not include products that may have gluten residue that has gone through hydrolysis or fermentation (for example barley containing beers that have been enzymatically clarified with a protease enzyme that cleaves gluten and results in a non-detect by the gluten ELISAs)



United States – Food Safety Modernization Act (FSMA) 2011

- Focus on preventative actions for food safety
- Foreign Supplier Verification Programs (FSVP): same preventative food safety standards apply to all food consumed in the United States, regardless of where it is manufactured
- "Food allergen controls" are preventative controls
 which are now required to be a written procedure to
 control allergen cross contact and ensure allergens
 are appropriately listed on the labels of packaged
 food products.



FDA จัดให้มีเอกลารฉบับแปลนี้เพื่อให้บริการแก่ผู้อ่านในประเทศต่างๆ เราหวังว่าเอกลารฉบับแปลนี้จะเป็นประโยชน์สำหรับคุณ แม้ว่าเราได้พยายามจัดหางานแปลที่ตรงกับฉบับภาษาอังกฤษมากที่สุดเท่าที่จะทำได้ แต่เราก็ตระหนักดีว่าเอกลารฉบับแปลอาจไม่ละเอียด หรือชัดเจน หรือสมบูรณ์เหมือนกับฉบับภาษาอังกฤษ ฉบับที่เป็นทางการของเอกลารนี้คือฉบับที่เป็นภาษาอังกฤษ

ข้อกำหนดที่สำคัญ: กฎสุดท้ายเกี่ยวกับโปรแกรมการตรวจสอบซัพพลายเออร์จากต่างประเทศ โดยสรุป

กฎหมายว่าด้วยความปลอดภัยด้านอาหาร (FSMA) ของ FDA เกี่ยวกับโปรแกรมการตรวจสอบชัพพลายเออร์ต่างประเทศ (FSVP) สำหรับผู้นำเข้าอาหารสำหรับมนุษย์และสัตว์ได้ข้อสรุปแล้ว โดยอีก 18 เดือน ธุรกิจบางกลุ่มจะต้องปฏิบัติตาม



Best Industry Practice in Supply Chain, Cleaning Validations and Verifications



Best Industry Practice in Supply Chains

- Supply chains are complex & sourcing all the information required can be challenging (for allergens and other topics)
- The supply chain of your ingredients is an extension of your own quality system
- Ensure that you have all questions answered BEFORE you start purchasing a product – procurement staff may be helpful
- Ensure that you have all information you need prior to bringing an ingredient on-site



Why should the food industry manage food allergens?

- protect allergic consumers
- food safety necessity
- consumers depend on food that is labelled correctly
- legal requirement for declaring food allergens
- costly to have non-compliance, allergen issues with consumers, recalls, withdrawals, re-labelling



What is allergen management?

The sum of policies, procedures and practices which contribute towards controlling allergens in a company

Allergen management is applicable to all levels and all areas of a company and sets the approach to the control and management of allergens





(in Allergen Management!)



Allergen Management Plan (AMP)

Having a robust Allergen Management Plan is the best way to avoid issues with allergens.

For example

Vendor Assurance to ensure that allergens are controlled in incoming ingredients

Training to ensure that every person in the organisation understands why there is a focus on allergens and how their job impacts the allergen status

Cleaning & other procedures to manage and control allergens at the manufacturing site

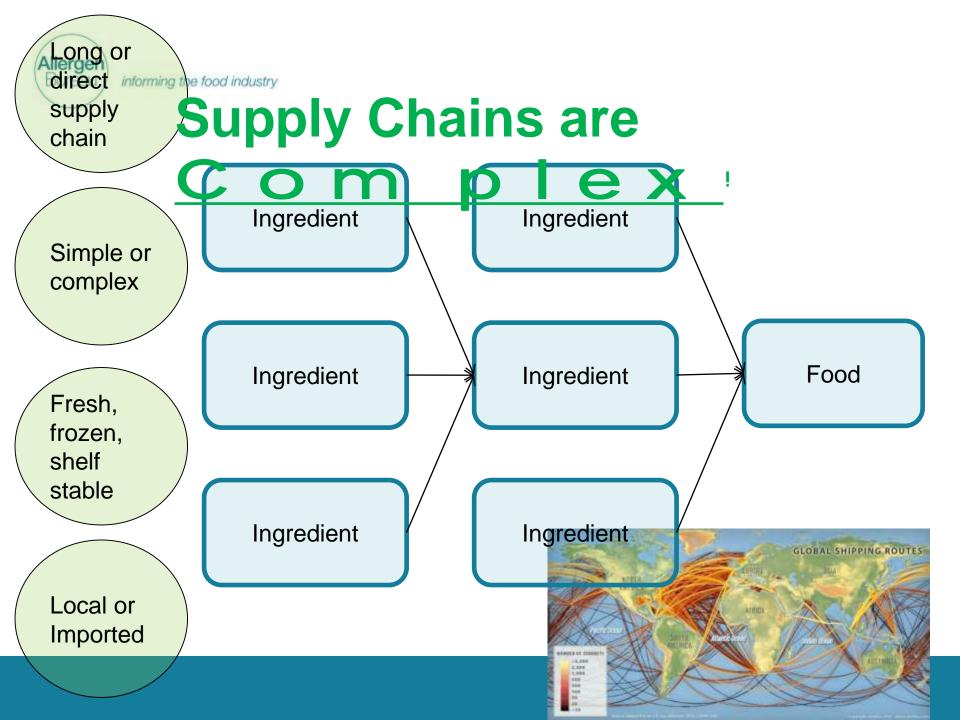


Vendor Assurance / Supply Chain Management

Deception, malicious tampering.... Maybe?

Lack of knowledge in the supply chain about allergens... Definitely!!!

AMP will help to identify, control, manage, monitor, verify, validate the intentional and unintentional presence of allergens.





Confidence in supplier information

Obtaining allergen information from ingredient suppliers should be a key component of your Vendor Assurance program

- always clarify information from supplier this exchange will assist in gaining confidence in supplier's allergen knowledge and handling
- query anything unusual or unexpected don't assume everything is correct
- keep asking questions until you are satisfied with the response do not accept data gaps



Confidence in supplier information - tools

- Risk assessment of EACH ingoing ingredient (allergen + other physical/chemical/biological risks)
- Use: Product specification (e.g. Product Information Form), what other products does the supplier manufacture/handle?, history with the company, 2nd and 3rd party allergen and/or food safety audits, certifications, ingredient which is inherently more challenging, additional questions to the supplier, what product is the ingredient going in to (vulnerable population?), minor or major component of the finished product
- ~ Auditing, allergen analysis



AFGC Product Information Form (PIF) v6.0

- a tool developed by the food industry in Australia and New Zealand to obtain and share information in a consistent and standardised manner
- ∼ Version 6.0 will be hosted on business to- business software
- Versions for samples, flavours, ingredients and retail ready products

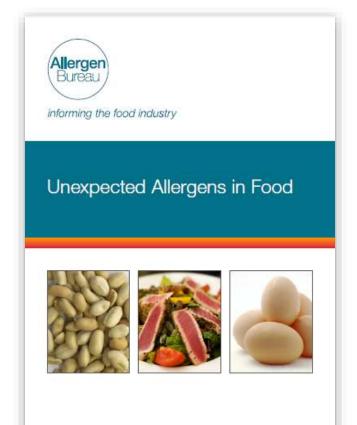
HELPING INDUSTRY TURN DATA INTO INFORMATION.





Unexpected Allergens in Food

- Questions to ask suppliers
- Available on the Allergen Bureau website



Soy Sauce	Does it contain wheat (in addition to soy)?
Spices	Does they contain any bases, carriers, free flowing agents (e.g. maltodextrin, flour, oleoresins, emulsifiers). If yes, what are they derived from e.g. wheat, maize, soy, egg?
Stabilisers	What are they derived from (e.g. soy, egg)?



Allergen Investigation

Example – one of the ingredients is **vegetable oil** Ask:

- What is the source of the oil? (Eg soy, peanut, canola)
- Does the oil contain any antioxidant?
- If so, is the antioxidant derived from soy?



Importing and exporting products and ingredients ~ some considerations

- different exemptions and limits for 'gluten free'
- different allergens for different jurisdictions
- some jurisdictions allow exemptions (e.g. highly refined ingredients, others don't)
- ~ translation challenges
- lack of understanding of different jurisdiction legislative needs



A quick note on Allergen Management on your own site....

- ~ Implement appropriate allergen management plan
- Build quality into every product including a focus on Allergen Management
- ~ Applicable to every role in the organisation



Raw materials

Scheduling

Processing aids

Cross contact allergens

Product development

Right label right pack

Rework

Cleaning

Allergen challenges in the manufacturing environment

Allergen declared on label

Processing environment

Production staff

Training and communication

Human error Processing equipment

Processing design



Cleaning for food manufacturers

- Cleaning is an essential part of food production!
- Cleaning (to remove "soil") and sanitation (to kill bacteria) prevents one product from being incorporated into another and controls microbiological risks
- Important for quality (taste, texture, colour) & safety (micro, allergens)



Validation and Verification of Cleaning Procedure (for allergens)

Validation: obtaining evidence that the a procedure is effective e.g. A cleaning procedure is effective to remove the allergen residue. Validation activities may include laboratory allergen analysis.

Verification: ongoing activities to ensure that the required standard has been met, usually at the conclusion of **each** clean. Verification activities may include strip tests, ATP, protein & visual standards.



Why Validate a Cleaning Process?

To ensure that your clean is doing what you want it to – i.e. Removing (or reducing to an acceptable level) allergenic residues

Validation of cleaning is an essential component of GMP & quality

Requirement of audit/standard



What to consider for a validation process

- Positive control (can the test pick up the allergen)
- Best Practice: Pass (not fail) 3 subsequent times for successful validation
- Is the allergen a particulate? Visually clean may be a better standard in this case. Assess sampling plan if using allergen analysis.
- Don't swab anything that looks dirty the clean wasn't successful!
- What will the threshold be?
- Consult an analyst
- Repeat annually or when any condition changes



What to consider for a verification process

- Must work in sync with validation
- Positive control
- Allergen specific tests are considered best practice
 - but surrogates may also be used esp where there is no specific test available
- Ongoing likely to be prior to production after a clean therefore should be a test that is quick & be able to carried out & interpreted correctly



Lupin



Recent Changes to FSC Standard 1.2.3: **Lupin**

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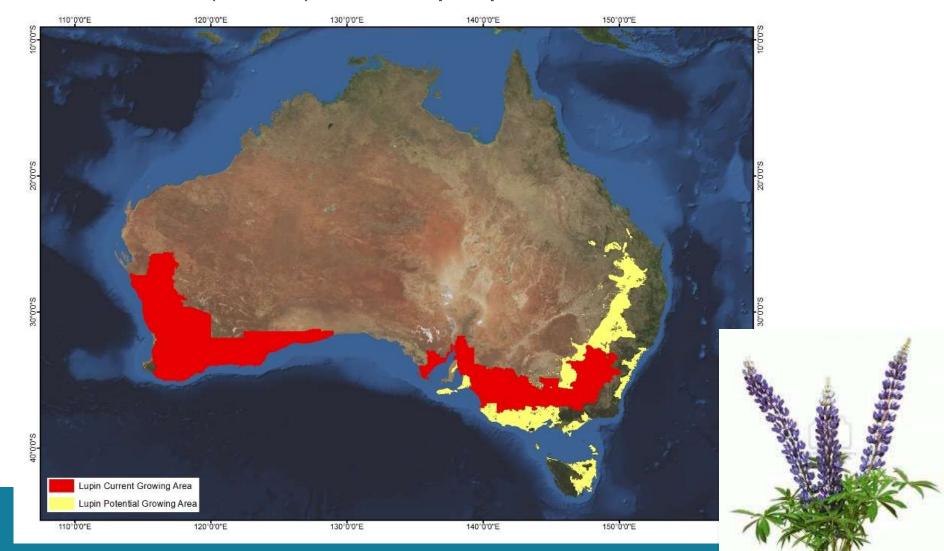
Recent Changes to FSC Standard 1.2.3: **Lupin**

- Lupin is a legume
- ~ Most lupin is grown in Australia
- It improves the soil and is grown in crop rotation with wheat (and oilseeds)
- Used in breads & other bakery items. Can be made into a protein isolate and used in a variety of products



What is Lupin?

Edible seed (kernel) of the lupin plant





Uses for Lupin

